

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 February 2002 (28.02.2002)

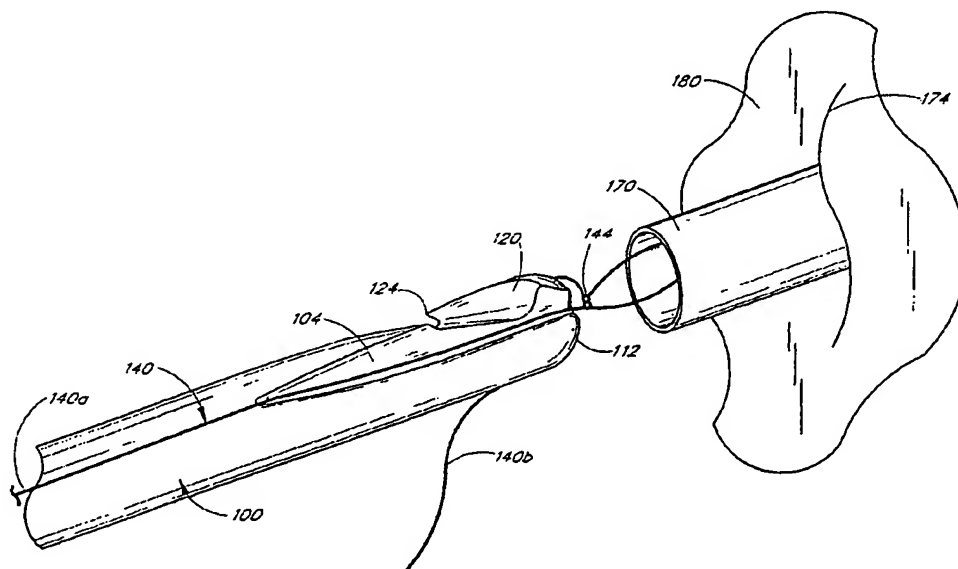
PCT

(10) International Publication Number
WO 02/15795 A2

- (51) International Patent Classification⁷: **A61B 17/04**
- (21) International Application Number: **PCT/US01/26724**
- (22) International Filing Date: 27 August 2001 (27.08.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/228,267 25 August 2000 (25.08.2000) US
- (71) Applicant (for all designated States except US): **SUTURA, INC.** [US/US]; 17080 Newhope Street, Fountain Valley, CA 92708 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **NOBLES, Anthony, A.** [US/US]; 8686 Tern Avenue, Fountain Valley, CA 92708 (US). **DECKER, Steven, E.** [US/US]; 1295 North Amelia, Anaheim, CA 92807 (US). **PETERSON, Rod** [US/US]; 23592 Windsong, Apartment 29I, Aliso Viejo, CA 92656 (US).
- (74) Agent: **ALTMAN, Daniel, E.**; Knobbe, Martens, Olson & Bear, LLP, 620 Newport Center Drive, 16th Floor, Newport Beach, CA 92660 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EC, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GI, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: **SUTURE CUTTER**



(57) Abstract: Suture cutter embodiments include elements for cutting back the leads of a suture after the suture has been tied into a knot, e.g., as a result of drawing tissue portions together. The suture cutter may include mechanisms which can be used to push and position a knot, so that a single device may be used to both push a knot and trim the excess material therefrom.

WO 02/15795 A2

WO 02/15795 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SUTURE CUTTER

Background of the Invention

Field of the Invention

The invention relates to suturing incisions, and more specifically, to the use of sutures for closing incisions in
 5 vessels and organs within a body, and cutting the ends of a suture once it has drawn together tissue portions.

Description of the Related Art

Surgeons frequently encounter the need to close incisions, wounds, or otherwise join tissue portions with a suture. After passing the suture through the tissue portions, the surgeon must tie the suture to draw the tissue portions together and prevent them from separating. When sutures are tied in a region having restricted access, such
 10 as the end of a tissue tract leading to an artery, the surgeon is presented with special challenges. Typically, the knot is formed outside the patient and then is pushed towards those tissue portions to be joined together.

Once a knot has been positioned against tissue portions such that they are securely fastened together, however, the surgeon must cut back the ends of the suture. This procedure can be difficult when using conventional instruments, particularly where access is limited. A reliable suture cutting procedure is needed whereby a surgeon can
 15 rapidly and accurately trim back the strands from a knot.

Summary of the Invention

According to one aspect of the invention, there is provided a method of severing end portions of a suture which extend from a sutured tissue portion. The method includes holding the suture end portions, and positioning an elongate member such that a distal portion of the elongate member is adjacent the sutured tissue portion. The method
 20 further includes positioning the suture end portions within at least one receptacle disposed at the distal portion of the elongate member, and severing the suture while the suture end portions are within said at least one receptacle by activating a severing element disposed adjacent the receptacle.

According to another aspect of the invention, there is provided an apparatus which includes a receptacle for juxtaposing portions of a suture to be connected to each other. The apparatus further includes a collar configured to
 25 surround the juxtaposed portions and a compression element positioned to compress the collar against the suture portions.

Brief Description of the Drawings

FIGURES 1-7 illustrate a first suture cutter embodiment, in which:

FIGURES 1 and 2 are end views of the suture cutter;

30 FIGURES 3A, 4A, and 5A are side elevation views of the suture cutter;

FIGURES 3B, 4B, and 5B correspond to the side elevation views of FIGURES 3A, 4A, and 5A, and show the suture cutter being used with a suture;

FIGURE 6 illustrates the suture cutter pushing a knot into a patient through a catheter sheath introducer (CSI);

35 FIGURE 7A shows the suture ends drawn across the suture cutter in preparation for cutting the suture ends;

FIGURE 7B illustrates the suture ends being cut as the suture cutter is rotated about its longitudinal axis, thereby forcing the suture ends against a cutting element; and

FIGURE 7C shows the suture cutter and the suture ends after the suture ends have been cut.

FIGURES 8-15 illustrate a second suture cutter embodiment, in which:

5 FIGURES 8 and 9 show perspective views of the distal end of the suture cutter;

FIGURES 10 and 11 show side views of the distal end of the suture cutter;

FIGURE 12 shows the full length of the suture cutter including the handle;

FIGURES 13 and 14 show the suture cutter with a suture, before and after the suture is thermally cut, respectively; and

10 FIGURE 15 shows the suture cutter being used to twist the suture ends.

FIGURES 16-24 illustrate a third suture cutter embodiment, in which:

FIGURE 16 shows a first cylindrical member, which has one end that acts like a knot pusher and another end that includes blade members for cutting suture material;

FIGURE 17 is a view of the knot pusher end of the first cylindrical member;

15 FIGURE 18 is a view of the blade member end of the first cylindrical member;

FIGURE 19 shows a second cylindrical member, which at one end has an extension member for rotating the second member, and at the other end has blade members for cutting suture material;

FIGURE 20 is a view of the blade member end of the second cylindrical member;

FIGURE 21 shows the assembled suture cutter, in which the second cylindrical member has been slid over
20 the first cylindrical member;

FIGURE 22 shows the blade member end of the assembled suture cutter; and

FIGURES 23 and 24 show the suture cutter with a suture, before and after the suture is cut, respectively, in which the suture is cut by rotating the second cylindrical element with respect to the first cylindrical element.

FIGURES 25-28 illustrate a fourth suture cutter embodiment, in which:

25 FIGURE 25 shows an expanded, isometric view of the distal end of the suture cutter;

FIGURE 26 is a cutaway which shows a welding element and a cutting element housed inside a compression tip for pressing a suture cylinder against ends of a suture;

FIGURE 27 shows a lump of suture material (which functions as a knot) which is formed when the suture and the suture cylinder are acted upon by the suture cutter;

30 FIGURE 28 shows another expanded, isometric view of the distal end of the knot pusher;

FIGURES 29-33D illustrate a fifth suture cutter embodiment, in which:

FIGURE 29 is a perspective view showing how the suture cutter captures ends of a suture with a lasso;

FIGURE 30 is a cross sectional view of the cutter as it is configured in FIGURE 29;

FIGURE 31 shows the lasso having drawn the suture ends through and out of a hypotube;

35 FIGURE 32 is a cross sectional view of the cutter as it is configured in FIGURE 31;

FIGURES 33A-D illustrate sequentially how a suture collar positioned in the cutter is used to form a fused portion in the suture which then acts like a knot.

Detailed Description of the Preferred Embodiment

Preferred embodiments of the invention are shown and described with respect to the accompanying figures.

5 The suture cutters herein may be used to cut the free ends of a suture extending from a knot that has closed up an incision within a patient (e.g., an incision in an organ or a vessel), or more generally, two tissue portions that have been drawn together.

An end view of a first suture cutter embodiment is shown in FIGURE 1. The suture cutter comprises an elongated, rod-shaped member 100 which includes an elongate recess 106 that extends longitudinally along opposed
10 sides of the member 100 and transversely across the distal end 112 of the member 100. The recess 106 thus includes a first longitudinal recessed portion 104, a transverse recessed portion 110 at the distal end 112 of the elongate member 100, and a second longitudinal recessed portion 116 shown in FIGURE 2, in which the member 100 has been rotated 180 degrees about its longitudinal axis with respect to its orientation in FIGURE 1. The second
15 recessed portion 116 is somewhat shallower and narrower than the recessed portions 104, 110. The longitudinal portions 104, 116 gradually taper from the distal end 112 of the elongate member 100 into the exterior surface of the member 100. The recessed portions 104, 110 and 116 are shaped as channels having semi-circular or semi-elliptical cross sections, such that ends extending from a surgical knot can be effectively guided within the recessed portions 104, 116 and the knot can be pushed by the recessed portion 110 of the member 100.

An angled recess 120 extends between the first and second recessed portions 104, 116 along a side of the
20 elongate member 100 at an angle relative to the longitudinal axis of the member 100. The recess 120 intersects the recessed portion 104 near the juncture of the portion 104 with the transverse portion 110. The recess 120 intersects the portion 116 at a location which is a significant distance proximal of the distal end 112. As indicated in FIGURES 1 and 2, a cutting element 124 is provided at the end of the recess 120 that is next to the transverse portion 110. The cutting element 124 comprises a cutting edge that is directed proximally and is formed by a recess 121 that extends
25 generally orthogonal to the recess 120 and between the recess 120 and the recessed portion 116. The recesses 120 and 121, as well as the cutting element 124 are more clearly shown in FIGURES 3A, 4A, and 5A, which are oriented at 120 degrees (about the longitudinal axis) with respect to each other.

FIGURES 3B, 4B, and 5B show the member 100 used with a suture 140 which has been tied into a self cinching knot 144. The member 100 is oriented so that respective end segment portions 140a, 140b of the suture are
30 disposed resting along and within the longitudinal recessed portions 104, 116, respectively, with the transverse portion against the knot 144. The knot 144 may be formed as described in Applicant's copending application entitled "Knot Pusher", Serial No. 09/571,759 filed on May 15, 2000 which is hereby incorporated by reference herein. In one embodiment, the suture 140 is a monofilament suture having a diameter of about 0.010". It may be introduced into the patient as described in U.S. Patent 5,860,990 entitled "Method and apparatus for suturing" and Applicant's copending
35 application 09/524,211 filed March 13, 2000 entitled "Suturing device and method", both of which are hereby

incorporated by reference herein. As described in more detail in the aforementioned copending application entitled "Knot Pusher", the practitioner may form a knot 144 utilizing a variety of knot tying techniques. One example is to tie two consecutive half hitches of the same orientation (e.g., two right hitches or two left hitches). One end segment of the suture 140 (e.g., the end segment 140b) remains loosely hanging off to the side while the practitioner pushes the distal end 112 of the elongate member 100 against the knot 144, with the knot 144 in the recessed portion 110. The member 100 fits snugly (e.g., 0.010" clearance) within a catheter sheath introducer (CSI) which has been introduced through an external incision 174 in the skin of the patient. The knot 144 is pushed through the CSI 170, as shown in FIGURE 6. The other end segment 140a is held firmly in the hand of the practitioner. In this manner, the two half hitches are pushed towards and up to an internal incision in the patient. Next, a single half hitch of the same type is formed (e.g., if two right half hitches were initially used, then a single right half hitch is formed) and pushed towards and up to the internal incision with the member 100, but with the practitioner now holding both end segments 140a, 140b securely in one hand. All consecutive loops are advanced in an analogous fashion towards the internal incision and are likewise of the same type, except for the last loop. The last loop is a half hitch of the other type, e.g., if the previous loops were all right half hitches, then a left half hitch is used, thereby creating a square knot, i.e., a tightened knot.

As mentioned, other types of knots and knot tying approaches may be used to form a tightened knot. Once a tightened knot has been formed against the internal incision, the practitioner cuts both end segments 140a, 140b so that no strands are left dangling outside of the patient's external incision 174. This is accomplished most easily by first removing the elongated member 100 completely from the patient while leaving the CSI 170 in place. The practitioner then pulls both end segments 140a, 140b taut and places both segments within the first longitudinal recessed portion 104. The elongate member 100 is reintroduced into the patient through the CSI 170 and pushed towards the tightened knot (at the internal incision) until the distal end portion 112 of the elongate member 100 butts up against the tightened knot. FIGURE 7A shows the relationship between the elongated member 100, the suture 140, and the tightened knot 144a at this point. Next, the practitioner rotates the elongated member 100 so that the suture 140 falls into the angled recess 120, where the suture is contacted by the cutting element 124, as shown in FIGURE 7B. While holding the suture end segments 140a, 140b taught, the practitioner continues to rotate the tubular member 100, while pulling the member 100 proximally, the force of the cutting element 124 against the suture cuts both end segments 140a, 140b, so that only short, stubby segments 140c, 140d of the suture remain joined to the tightened knot 144a, as shown in FIGURE 7C. At this point the loose end segments 140a, 140b are removed from the patient, along with the CSI 170. The external incision 174 is then sutured closed.

A second suture cutter embodiment 200 is shown in FIGURE 8. A recessed, transverse, channel-shaped portion 204 at a distal end 202 of the suture cutter 200 extends from one side of the cutter 200 to the other. The portion 204 is configured for guiding suture strands and optionally for pushing knots. Two side resistive heater elements 210, 211 (e.g., copper) are located on either side of the suture cutter 200 within the channel-shaped portion 204 at respective ends thereof and about 1 cm longitudinally from the tip of the distal end of the cutter. The side

resistive heater elements 210, 211 are electrically connected to respective electrically insulated lead lines 214a, 215a which pass through the cutter 200 and are visible through respective grooves 216a, 217a. A centrally located resistive heater element 220 (shown in dashed lines), disposed in the center of the portion 204 at the tip of the distal end 202, is likewise connected to an electrically insulated lead line 222a which is visible through a groove 224a. The

5 resistive heater element 220 resides within the cutter 200 near the recessed portion 204 and is not exposed to the outside environment. FIGURE 9 shows the cutter 200 rotated by 180 degrees about its longitudinal axis and illustrates that the resistive heater elements 210, 211 are electrically coupled to electrically insulated lead lines 214b, 215b, respectively, which, together with lead lines 214a, 215a, complete the circuit through the resistive heater elements 210, 211. Likewise, the centrally located resistive heater element 220 is electrically coupled to an

10 electrically insulated lead line 222b which, with the lead line 222a, form an electrical circuit. The lead lines 214b, 215b, 222b are located in respective grooves 216b, 217b, 224b. Side views of the second suture cutter embodiment 200 are illustrated in FIGURES 10 and 11.

A full length view of the suture cutter 200 is shown in FIGURE 12. The suture cutter 200 includes a handle 230 at its proximal end. The handle 230 includes a three-position switch 234 coupled to an LED 238 which indicates

15 whether the switch 230 is off, in the first on-position (for heating the centrally located resistive heater element 220), or in the second on-position (for heating the side resistive heater elements 210, 211). The handle 230 further includes a charging battery 242 (shown in dashed lines). The battery 242 supplies power to the resistive heater elements 210, 211, 220 as controlled by the switch 234.

The suture cutter 200 may be used to push a knot in a fashion analogous to that of the first suture cutter

20 embodiment described above. In particular, the recessed portion 204 may advantageously engage a knot which is then pushed by the practitioner through a CSI and towards an internal incision in a patient. Although a tightened knot may be formed, for example, by repeatedly pushing half hitches through the CSI as described above, the suture cutter 200 offers alternatives to this approach. For example, once a knot (or even crossed suture end segments) has been positioned just proximal to the internal incision, power may be supplied to the centrally located resistive heater element

25 220. As illustrated in FIGURE 13, this causes the element 220 to heat up. Sufficient heat is applied to plastically deform the suture material in the knot, by partially melting the suture material to join the end segments together. However, the heat is not so great as to sever the suture material. Next, the two end segments 140a, 140b of the suture 140 are held taut by the practitioner within the channel portion 204 so that they contact the resistive heater elements 210, 211, respectively. Power is then supplied to the elements 210, 211 located on either side of the suture

30 cutter 200. Referring to FIGURE 14, the resistive heater elements 210, 211 supply sufficient heat to cause the suture to be severed by melting, leaving short segments 140c, 140d of suture material adjoining the formed knot 250. The end segments 140a, 140b and the suture cutter 200 can then be removed from the patient along with the CSI.

In an alternative method, the two end segments 140a, 140b may be held taut on respective sides of the suture cutter 200 by the practitioner, and the suture cutter 200 is pushed towards the internal incision. When the

35 distal end 202 of the suture cutter 200 is near the internal incision, the suture cutter 200 is rotated about its

longitudinal axis, so that the end segments 140a, 140b contact and twist about each other, as shown in FIGURE 15. The practitioner may then apply power to the centrally located resistive heater element 220 to fuse the twisted suture and thereby prevent it from unraveling. The twisted suture effectively becomes a knot that is held together by fused suture material. The end segments 140a, 140b may be severed by melting using the side resistive heater elements 5 210, 211 as described previously. The end segments 140a, 140b and the suture cutter 200 can then be removed from the patient along with the CSI.

A third suture cutter embodiment is shown in FIGURES 16-24. FIGURE 16 shows a side view of a first cylindrical member 300 which at one end 302 includes a channel-shaped, recessed, transverse portion 304 for engaging and pushing a knot. An end view of the recessed portion 304 is shown in FIGURE 17. At the other end 306 10 of the cylindrical member 300 is a dome shaped element 308 and four elongate blade members 310 which are circumferentially arranged around the cone-shaped element 308. The end 306 of the cylindrical member 300 is seen more clearly in the end view of FIGURE 18. Each of the blade members 310 projects longitudinally and terminates in a terminal end 314 which is rounded or otherwise sufficiently dull that it can not damage tissue. The blade members 310 have longitudinal edges 318, disposed on the outward side thereof, which are sharp so that they can cut through 15 suture material.

A second cylindrical tubular member 322, illustrated in FIGURE 19, has an interior passage sized so that it can be slid over the first cylindrical member 300. At one end 324 of the second cylindrical member 322, four longitudinally extending, elongate blade members 326 are provided which likewise terminate in flattened or rounded ends 330 that are dull. The blade members 326 have longitudinal edges 334 on the inward side thereof which are 20 sharpened for cutting suture material. An end view of the second cylindrical member 322 is shown in FIGURE 20. The cylindrical member 322 further includes a extension member 338 such as a hexagonal nut for rotating the second cylindrical member 322.

The first and second cylindrical members 300, 322 are operably coupled to form a suture cutter 342 by sliding the second cylindrical member 322 over the first cylindrical member 300, as shown in FIGURE 21. The 25 cylinders 300, 322 are rotatable relative to each other, and the blade members 310, 326 are configured so that the sharpened edge 334 of the blade members 326 and the sharp edges 318 of the blade members 310 pass immediately adjacent to each other during rotation. The tolerance between the blade members 310 and the blade members 326 is such that a suture extending between the blade members 310, 326 will be cut when the sharp edges 318 and 334 move past each other. An end view of the device 342 showing the blade members 310, 326 is shown in FIGURE 22. 30 The spaces between each pair of blade members 310 form respective slots for receiving a segment of suture.

In operation, the practitioner may use the end 302 of the first cylindrical member 300 to push a knot through a CSI towards an incision within a patient and form a tightened knot just proximal to the internal incision, as discussed in connection with the other methods disclosed herein. The device 342 is then retracted from the patient and turned around so that the end of the device with the blade members 310, 326 faces the CSI. Each of the end segments 35 140a, 140b of a suture is placed into different suture receiving slots formed by the blade members 310, as illustrated

in FIGURE 23. The device 342 is reinserted into the patient and pushed through the CSI towards the knot (which is proximal to the internal incision) until the dome shaped element 308 contacts the knot. At this point, the practitioner rotates the second (outer) cylindrical member 322 with respect to the first (inner) cylindrical member 300 by grasping and turning the extension member 338. As a result of this rotation, the suture material is cut between the blade members 310, 326, as shown in FIGURE 24.

5 A fourth embodiment 400 is shown and described with respect to FIGURES 25-28. The device 400 functions both as a knot former and suture cutter. An exploded, isometric view of the distal end 404 of the device 400 is shown in FIGURE 25. The two end segments 140a, 140b of a loop of the suture 140 pass through a suture collar or cylinder 408 which is preferably made of the same material as the suture itself, e.g., monofilament polypropylene. The two end segments 140a, 140b also pass through a welding element 412, a cutting element 416, a
10 compression tip 420, a lumen 422 in a multi-lumen inner tube 424, a side hole 426 (FIGURE 28) in the inner tube, and a side slot 427 in an outer compression tube 428 which registers with the hole 426. As illustrated most clearly in the cutaway of FIGURE 26, the welding element 412 and the cutting element 416 are configured such that they make a good mechanical contact with the inside of the compression tip 420. Prior to actuation, the suture collar 408 is placed
15 within the welding element 412 so that the proximal end of the suture collar is flush with the proximal end of the welding element, whereas the distal end of the suture collar 408 extends slightly beyond the distal end of the welding element.

The compression tip 420 is integrally joined to the inner multi-lumen tube 424, which may be the same material as the compression tip (e.g., plastic), or alternatively, the compression tip may be metal with the inner tube
20 424 being plastic. The outer compression tube 428 is slidably mounted on the inner tube 424 and the compression tip 420. The compression tip 420 has a pair of relief slots which allow its distal end portion to flex inwardly. When the outer compression tube 428 is slidably forced over the compression tip 420, the compression tip flexes and presses the suture collar against the end segments 140a, 140b. The suture collar 408 and the end segments 140a, 140b may then be fused together by activating the welding element 412 to apply heat to the suture collar 408. Sufficient heat is
25 applied by the welding element 412 to plastically deform the collar and partially melt the suture material to cause the suture ends and suture collar to fuse together. The heat, however should not be so great as to sever the suture. Such fusion forms a bulb or fused mass 430 in the suture 140 which effectively acts as a knot, as shown in FIGURE 27. The end segments 140a, 140b proximal to the suture collar 408 may then be severed from the suture collar by activating the cutting element 416 to apply sufficient heat to the suture ends so that they are severed. The cutting
30 element 416 is spaced proximally from the suture collar so that such cutting leaves behind short, stubby segments 140c, 140d of suture material attached to the mass 430 (see FIGURE 27). The welding element 412 and the cutting element 416 comprise resistive elements that generate heat when electrical current is supplied. In the case of the welding element 412, heat is transferred to the suture collar 408 and the end segments 140a, 140b, so that the suture cylinder and the suture strands meld or fuse together. On the other hand, the heat applied by the cutting
35 element 416 to the end segments 140a, 140b is sufficient to melt through the strands. After the welding element 412

and the cutting element 416 have been activated in turn and the mass 430 is formed, the suture cutter 400 may be cleaned and reused or simply discarded in favor of a new suture cutter.

Electrical current is supplied to the welding element 412 and to the cutting element 416 through respective pairs of lead lines (not shown), which pass through lumens 432, 434 in the inner extrusion tube 424 and lumens 436, 438 in the compression tip 420. The lumens 436, 438 are shown in FIGURE 28. When the inner extrusion tube 424 and the compression tip 420 are joined during the fabrication process, the lumens 432, 434 are aligned with the lumens 436, 438, respectively, so that the lumens 432, 436 form one continuous lumen, as do the lumens 434, 438. The lumen pair 432, 436 may be used to carry lead lines to the welding element 412, whereas the lumen pair 434, 438 may be used to carry lead lines to the cutting element 416. (The lumen 422 in the inner extrusion tube 424 and a lumen 446 in the compression tip 420 are used to receive the end segments 140a, 140b.) A power supply (not shown) connected to the lead lines may be advantageously programmed so that the welding element 412 and the cutting element 416 are supplied with the appropriate amount and duration of current.

The end segments 140a, 140b may be loaded into the suture cutter 400 by drawing them through the suture collar 408 (which is surrounded by the welding element 412), the cutting element 416, the compression tip 420, the lumen 422 in the inner extrusion 424, the hole 426 in the inner extrusion 424, and the slot 427 in the outer compression tube 428. For this purpose, a suture leader comprising a wire 440 having a grasping portion 441 (see FIGURE 25) at its distal end for holding the end segments 140a, 140b may be used, such as that described in Applicant's copending Application No. 09/571,759 entitled "Knot Pusher", filed on May 15, 2000. The wire 440 is passed through the slot 427 and is pushed distally until the grasping portion exits the suture collar 408. The end segments 140a, 140b are then inserted into a loop of wire at the grasping portion to secure the segments to the wire 440. The wire is then retracted back through the distal end 404 of the suture cutter 400. The slot 427 may be 1-2 cm in length and is aligned with the hole 426, so that when the outer compression tube 428 is urged forward (say, 5 mm) to compress the compression tip 420, the end segments 140a, 140b are not caught between the inner extrusion 424 and the outer compression tube 428.

It will be understood by those skilled in the art that embodiments similar to the one shown in FIGURES 25-28 may be employed which rely either on (i) compression forces alone (without the use of a thermal element) to secure the suture collar 408 to the suture end segments 140a, 140b, or alternatively, (ii) a thermal element alone (without the use of a compression tip) to fuse the suture collar 408 to the suture end segments 140a, 140b.

FIGURES 29-33D illustrate a fifth embodiment 500 which acts as a suture cutter while effectively forming a knot as well. As illustrated, the cutter 500 comprises a hypotube 506 that extends from a main body 515. A carriage member 512 is slidably mounted to ride over the hypotube 506. As shown in FIGURES 29 and 30, a lasso 504 comprised of a loop of flexible line, such as a strand or string, has end portions 504a, 504b that are attached to the carriage member 512. When the carriage is at the distal end of the hypotube 506, the loop is open and extends forward of the hypotube so as to receive and surround end segments 140a, 140b of a suture 140. By way of example, the lasso 504 may be comprised of a 0.006" diameter silk strand.

As best shown in FIGURE 30, the end portions 504a, 504b of the lasso 504 extend through an opening in the distal end of the hypotube 506 and out of a side window 505 of the hypotube. The terminal ends of the portions 504a, 504b may be secured within a recess 507 of the carriage member 512 with a bonding material such as cyanoacrylate. Secured within the hypotube 506 is a tubular member that includes a proximal tubular portion 508a and a distal tubular portion 508b which have been bonded together. The proximal portion 508a may be plastic, and the distal portion 508b is preferably a high temperature plastic. A plunger 528 is mounted to slide longitudinally within the lumen of the tubular members 508a, 508b. A suture collar 532 comprising a generally cylindrical tubular member is mounted distal to the plunger 528, in spaced relationship thereto, and within a distal portion 524 of the hypotube 506. The plunger 528 is sized to apply force to the proximal end of the suture collar 532. Thus, the lasso 504 extends from the carriage 512 through the window 505, between the plunger 528 and suture collar 532, through the central bore of the suture collar 532, and out of the distal end of the hypotube 506.

The carriage member 512 slides over the hypotube 506, so that the practitioner may retract (or advance) the carriage member with respect to the hypotube. As mentioned above, when the carriage 512 is advanced to the distal end of the hypotube 506, the lasso 504 is fully open so as to receive suture end segments 140a, 140b. As the carriage member 512 is retracted, the end portions 504a, 504b of the lasso 504 are pulled in a proximal direction, so that the size of the loop progressively decreases and the lasso 504 tightens around the suture end segments 140a, 140b, with the lasso pulling the segments 140a, 140b into the distal end of the hypotube 506. As the practitioner continues to retract the carriage member 512, the lasso 504 is pulled through the window 505, and the suture end segments 140a, 140b are carried by the lasso through and out of the window 505 in a proximal direction. As shown in FIGURE 31, the carriage member 512 may be completely retracted until it reaches a detent member 516 (seen in FIGURE 29) which holds the carriage member in a proximal position. At this point, the entire lasso 504 has been pulled from the window 505 such that the lasso is free to enlarge and is no longer tightly holding the proximal ends of the suture end portions 140a, 140b which now hang loosely outside the hypotube 506, as illustrated both in FIGURE 31 and the cross sectional view of FIGURE 32.

Referring to FIGURES 33A, 33B, 33C, and 33D, the practitioner then holds the ends of the suture and advances the hypotube 506 into the patient and toward the suture site through a catheter sheath introducer (CSI) 170. The distal portion 524 of the hypotube 506 is positioned at the suture site next to tissue portions 526a, 526b within the patient through which the suture 140 passes, so as to draw the tissue portions 526a, 526b together. Referring to FIGURE 33A, the plunger 528, which may be comprised of a hard, high temperature plastic, is then moved distally by applying force to a handle 520 (FIGURE 31). Such distal movement drives the plunger against the suture collar 532 which surrounds the suture end segments 140a, 140b.

As illustrated in FIGURE 33B, a coiled heating element 536 surrounds the suture collar 532. The collar 532 melts or deforms when subjected to heat and may be comprised of the same material as the suture 140, e.g., polypropylene. As the plunger 528 is advanced distally against the suture collar, the heating element is activated to soften the suture collar 532. The distal end of the hypotube has an annular inward projection which forms an opening

that is significantly smaller than the diameter of the suture collar 532 so that application of longitudinal force to the collar 532 by the plunger 528 compresses the heated collar against the annular projection. Such compression causes the collar to plastically deform inwardly around and against the suture ends 140a, 140b, so as to close the opening through the collar 532. In this way, the suture collar 532 is effectively extruded out the distal portion 524 of the
5 hypotube 506. As illustrated in FIGURE 33C, such extrusion causes the collar 532 and suture end segments 140a, 140b to fuse together into a fused mass 534 which effectively acts as a knot (similar to the fused portion 430 of FIGURE 27) to keep together the tissue portions 526a, 526b that have been sutured. To this end, the distal end of the fused mass 534 is preferably adjacent the tissue portions 526a, 526b.

After the fused mass 534 is formed, the portions of the free ends of the suture that extend from the mass
10 will be adjacent to and exposed to the coiled heating element 536 (since the fused mass 534 is now outside the hypotube--see FIGURE 33C). The heating element 536 is activated to sever the end segments 140a, 140b from the rest of the suture 140. The practitioner may then withdraw the device 500 from the CSI 170 and out of the patient, leaving the fused mass 534 behind in the patient, as shown in FIGURE 33D. While the preferred embodiment utilizes both heat and compression to cause the collar 532 to lock the suture end portions together, it will be appreciated that
15 other embodiments may use only compression, without heat, and still other embodiments may use only heat, without compression.

Although this invention has been described with reference to specific embodiments, the descriptions are intended to be illustrative of the invention and are not intended to be limiting. Various modifications and applications may occur to those skilled in the art without departing from the true spirit and scope of the invention as defined in the appended claims.

20

WHAT IS CLAIMED IS:

1. A method of severing end portions of a suture which extend from a sutured tissue portion, comprising:
 - holding the suture end portions;
 - 5 positioning an elongate member such that a distal portion of the elongate member is adjacent the sutured tissue portion;
 - positioning the suture end portions within at least one receptacle disposed at the distal portion of the elongate member; and
 - severing the suture while the suture end portions are within said at least one receptacle by
 - 10 activating a severing element disposed adjacent the receptacle.
2. The method of Claim 1, wherein said holding comprises holding said end portions, with said end portions extending along a tissue tract.
3. The method of Claim 1, wherein said holding comprises applying tension to said end portions.
4. An apparatus for severing end portions of a suture, in which the suture extends from a sutured

15 tissue portion, comprising:
 - an elongate member having a distal end portion, said elongate member sized to be inserted into a tissue tract with said distal end portion of said elongate member adjacent the sutured tissue portion, said distal end portion including:
 - at least one suture receptacle; and
 - 20 a suture severing element disposed adjacent to said at least one suture receptacle such that at least one suture end portion within said at least one suture receptacle is severed upon activation of said severing element.
 5. The apparatus of Claim 4, wherein said elongate member comprises a single suture receptacle.
 6. The apparatus of Claim 4, wherein said elongate member comprises a plurality of suture

25 receptacles.
 7. The apparatus of Claim 4, wherein said elongate member comprises a single suture severing element.
 8. The apparatus of Claim 4, wherein said elongate member comprises two suture severing elements.
 9. The apparatus of Claim 4, wherein said suture severing element comprises a plurality of blade

30 pairs.
 10. The apparatus of Claim 4, wherein said suture severing element comprises at least one heating element which melts through the suture.
 11. The apparatus of Claim 4, wherein said suture severing element comprises a blade which cuts through the suture.

12. The apparatus of Claim 4, wherein said elongate member includes at least two longitudinal members which are rotatable with respect to each other, said longitudinal members including respective blade members at respective distal end portions of said longitudinal members, said blade members severing the suture upon rotation of one of said at least two longitudinal members with respect to another of said at least two longitudinal members.

13. The apparatus of Claim 4, comprising:
at least two suture receptacles which form opposing guides for receiving the suture end portions, said guides permitting the suture end portions to be twisted about each other; and
a heating element which heats the twisted end portions such that said twisted end portions are fastened together.

14. The apparatus of Claim 13, comprising at least one additional heating element which severs the suture end portions to separate the fastened end portions from free ends of the suture.

15. The apparatus of Claim 4, wherein said at least one suture receptacle includes a distal pusher portion configured to push a knot.

16. The apparatus of Claim 15, wherein said distal pusher portion is recessed with said elongate member.

17. The apparatus of Claim 13, wherein said heating element heats the twisted end portions such that said twisted end portions are fused together.

18. An apparatus, comprising:
a receptacle for juxtaposing portions of a suture to be connected to each other; and
a heating element positioned to apply heat to the juxtaposed suture portions such that the juxtaposed suture portions are fastened together.

19. The apparatus of Claim 18, wherein said receptacle is configured to cause said juxtaposed portions to twist about each other in response to rotation of said receptacle, and wherein said heating element fuses the twisted, juxtaposed suture portions together.

20. The apparatus of Claim 18, comprising a collar configured to surround the juxtaposed suture portions, said heating element disposed to apply heat to said collar.

21. The apparatus of Claim 20, wherein said heating element fuses the collar to the suture portions.

22. The apparatus of Claim 18, comprising:
a collar which surrounds the juxtaposed suture portions; and
a compression element which compresses said collar against said juxtaposed suture portions.

23. An apparatus, comprising:
a receptacle for juxtaposing portions of a suture to be connected to each other;
a collar configured to surround the juxtaposed portions; and
a compression element positioned to compress said collar against said suture portions.

24. The apparatus of Claim 23, comprising a heating element positioned to apply heat to said collar such that said collar readily deforms in response to said compression.

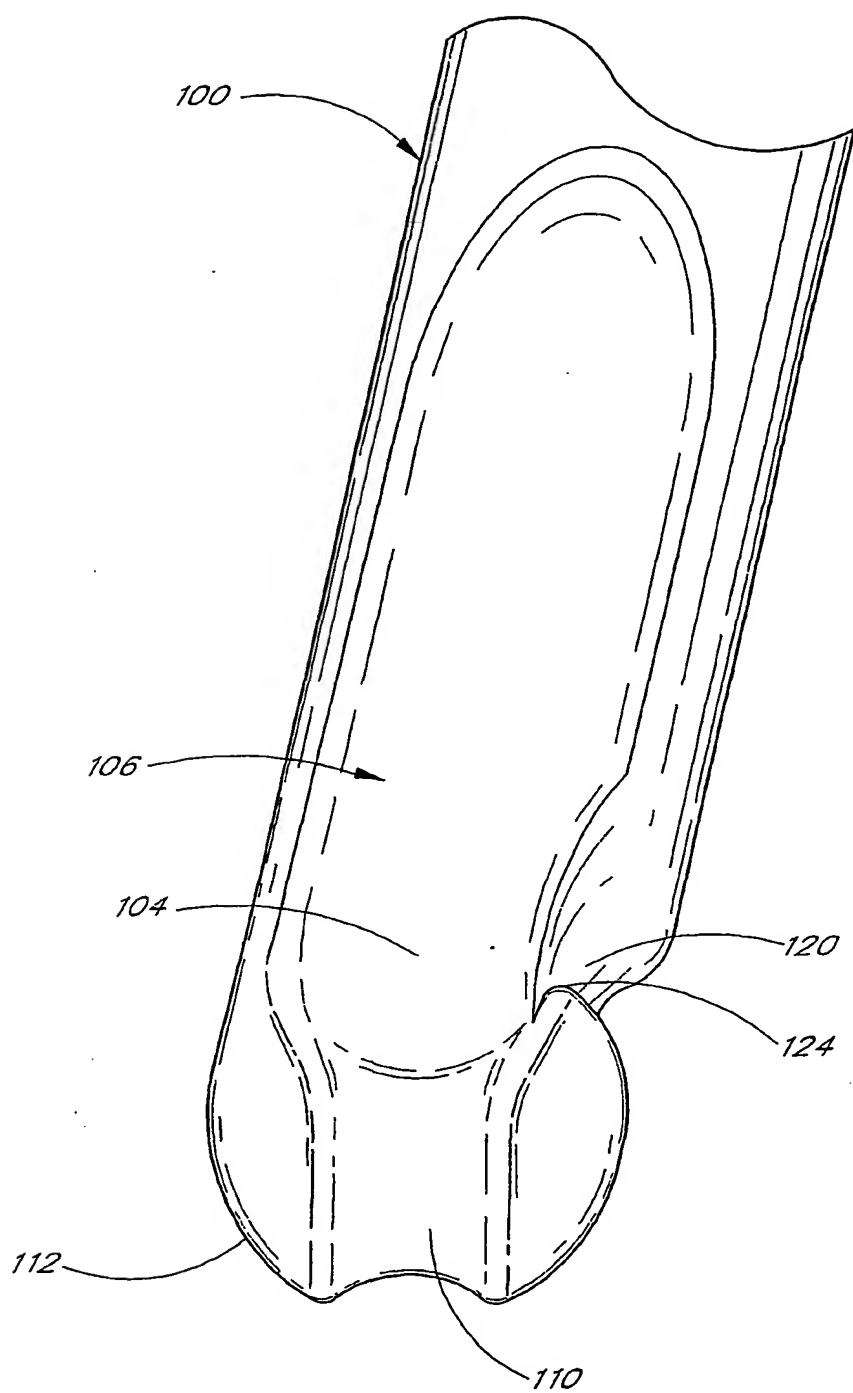


FIG. 1

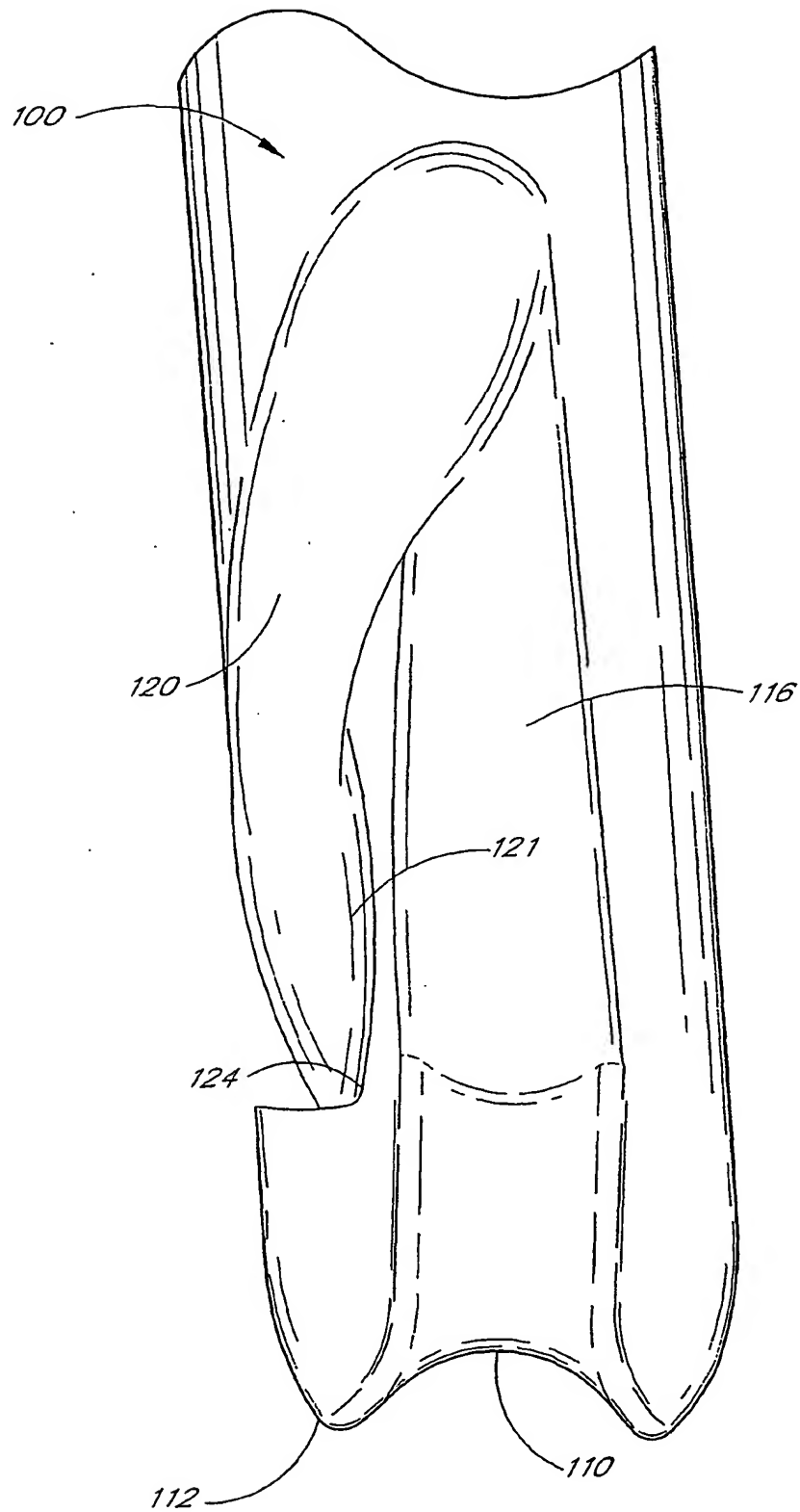


FIG. 2

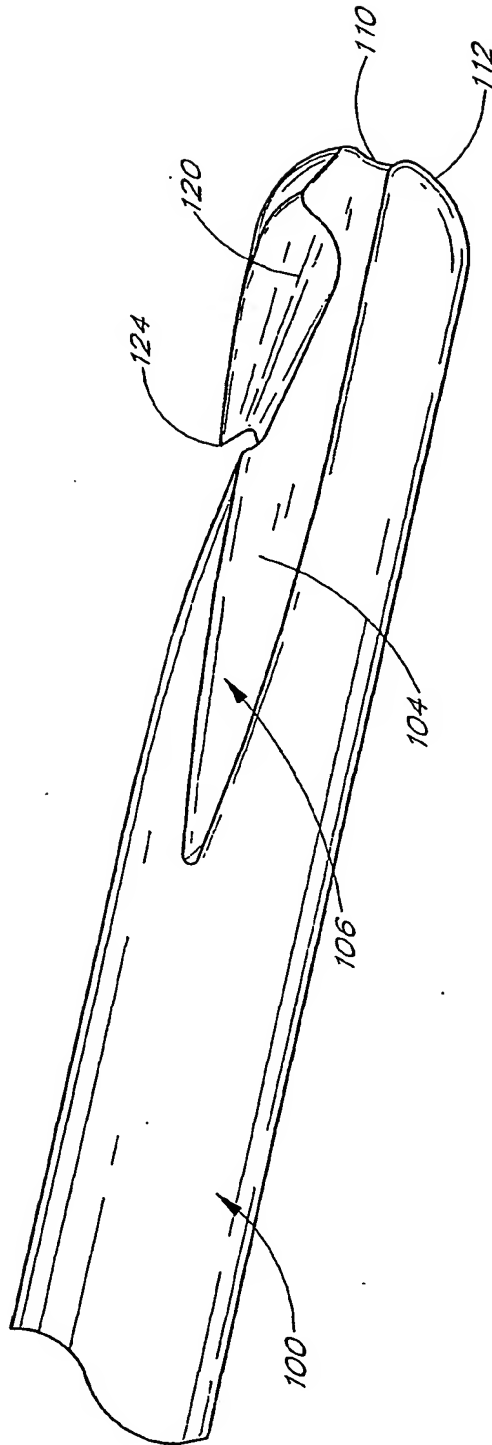


FIG. 3A

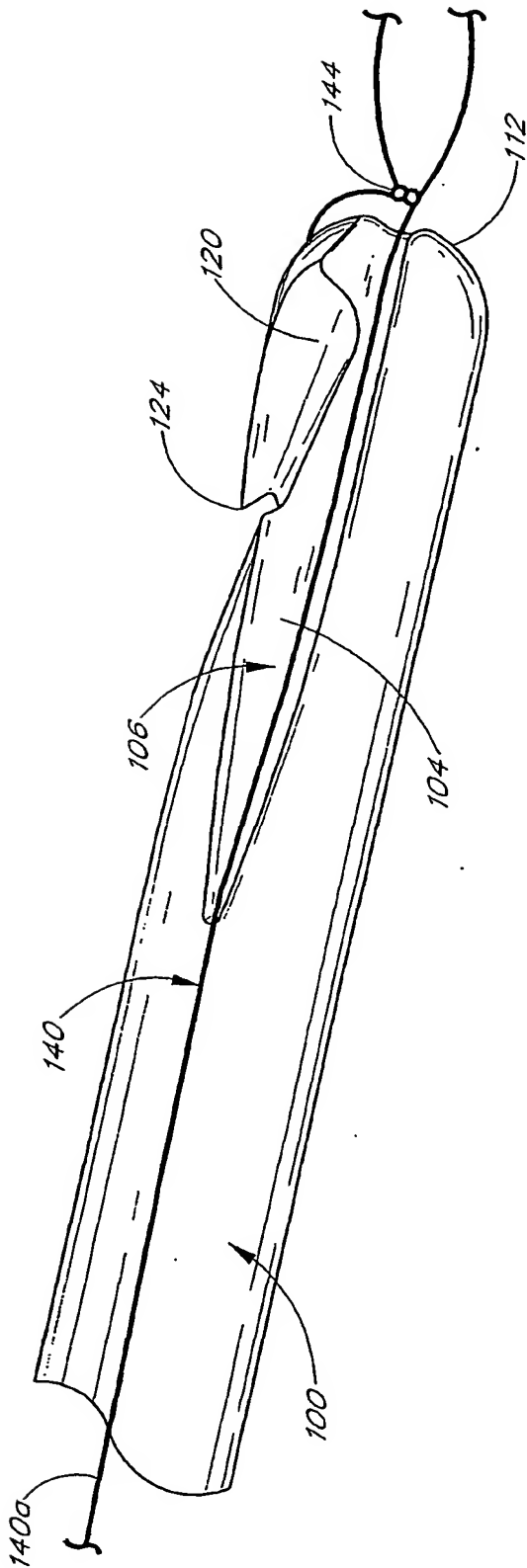


FIG. 3B

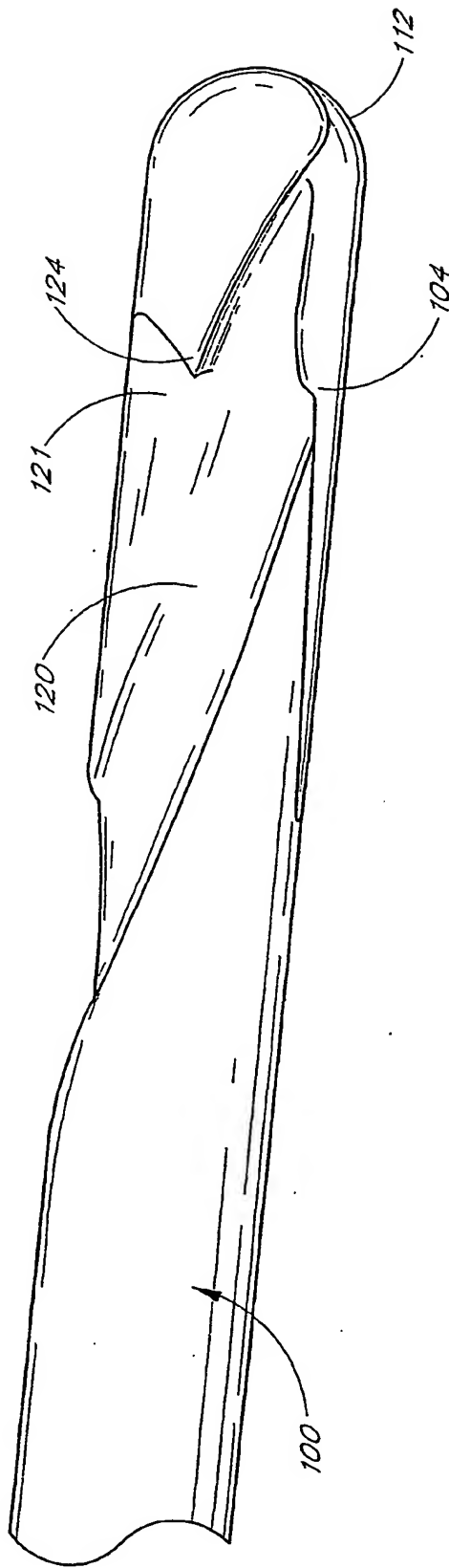


FIG. 4A

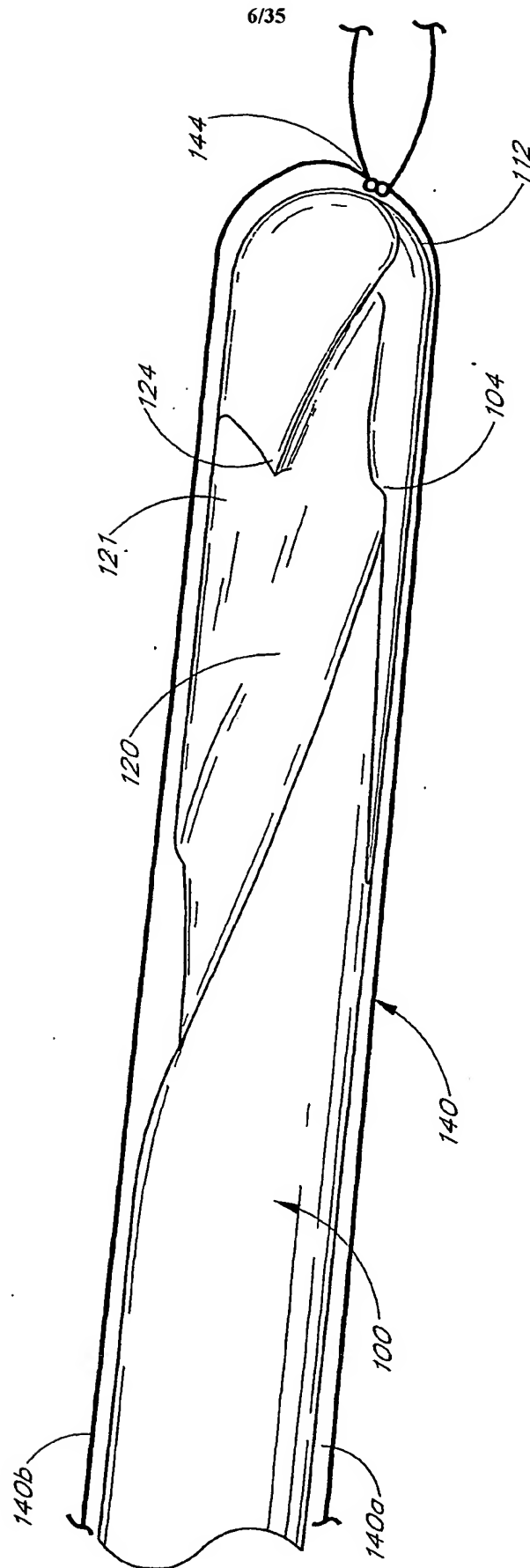


FIG. 4B

7/35

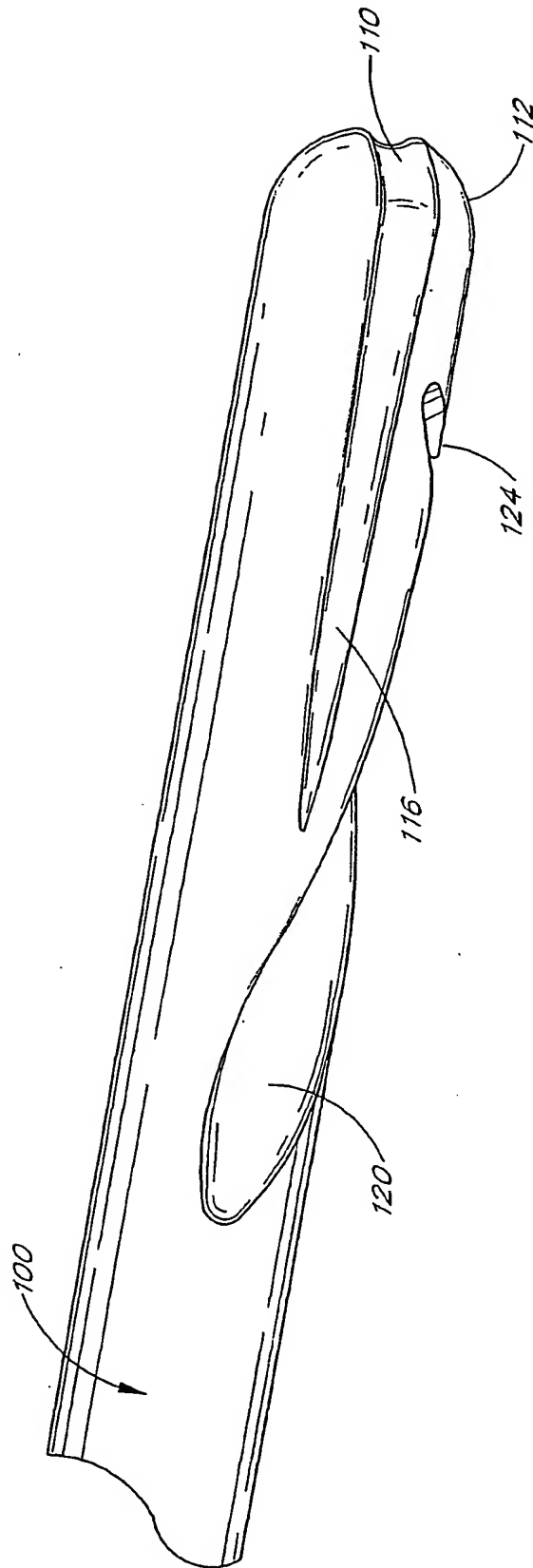


FIG. 5A

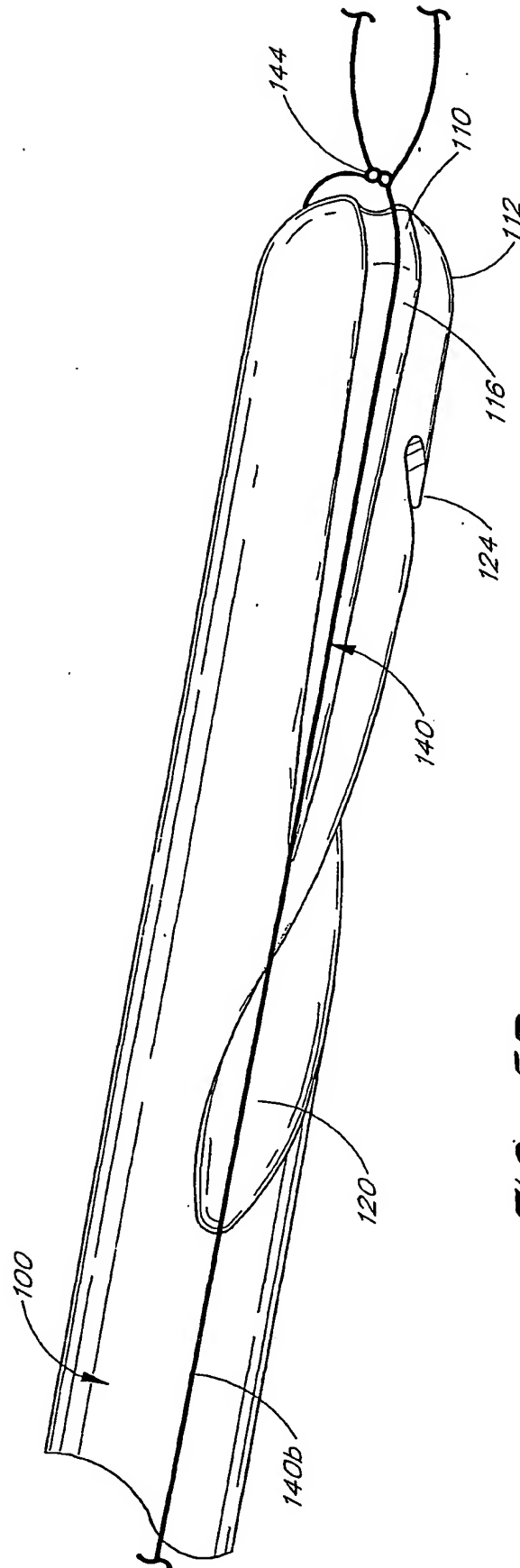
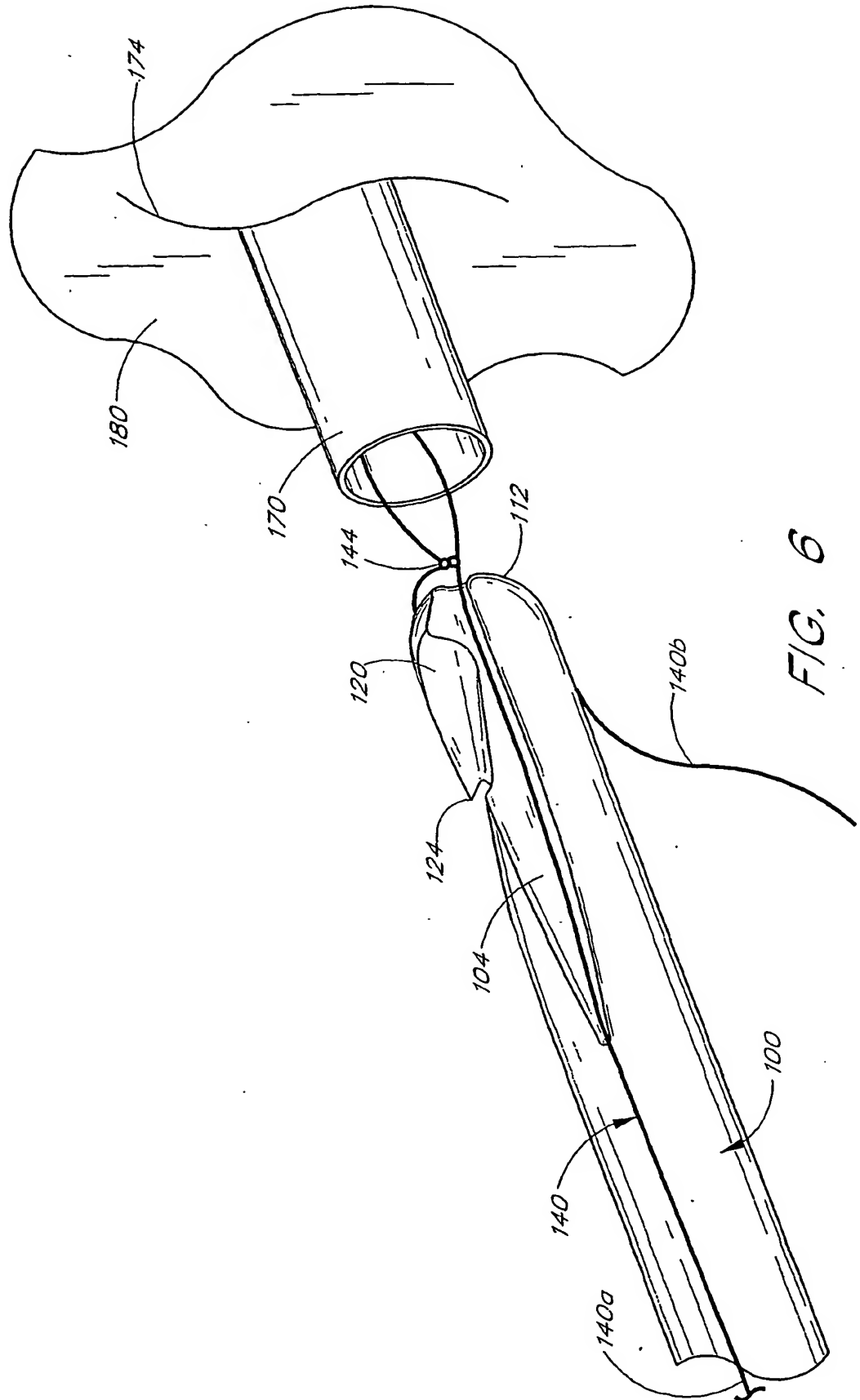


FIG. 5B



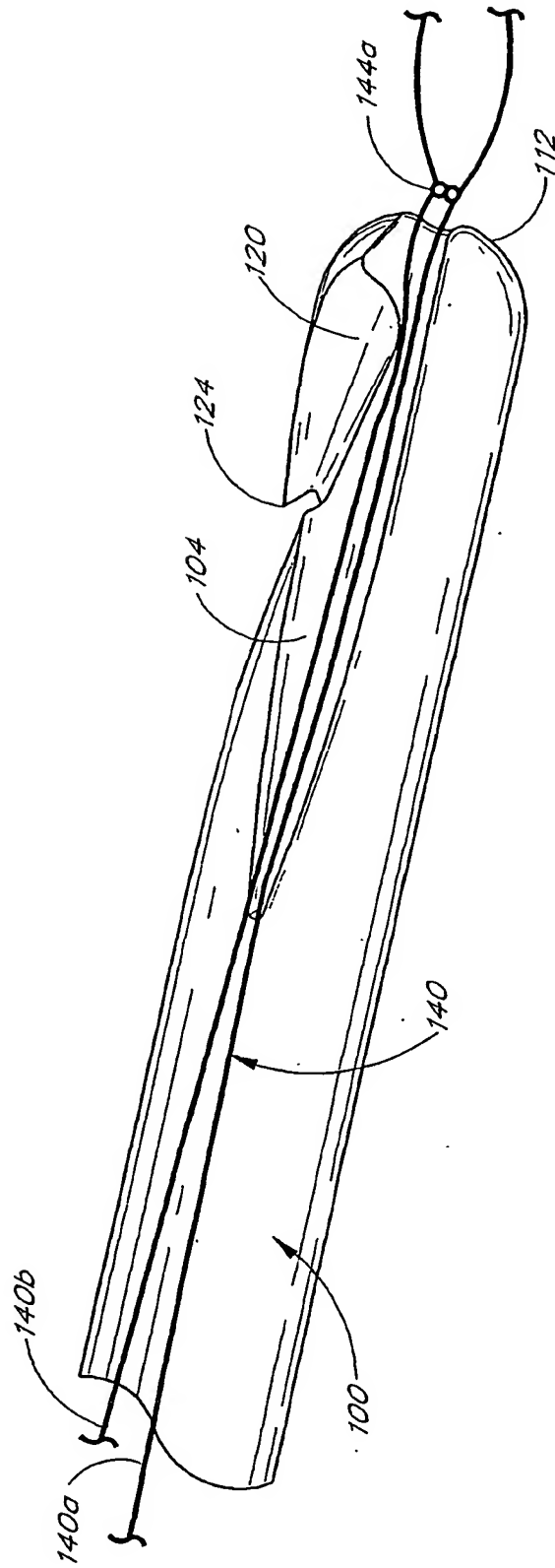


FIG. 7A

11/35

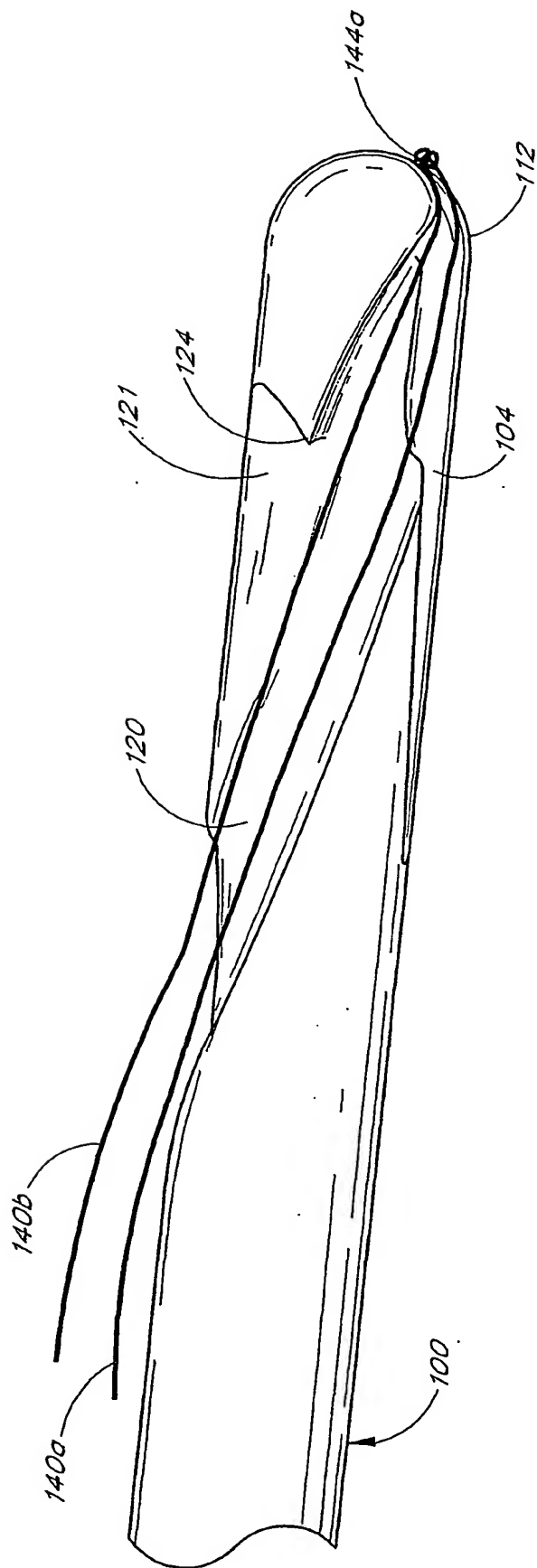


FIG. 7B

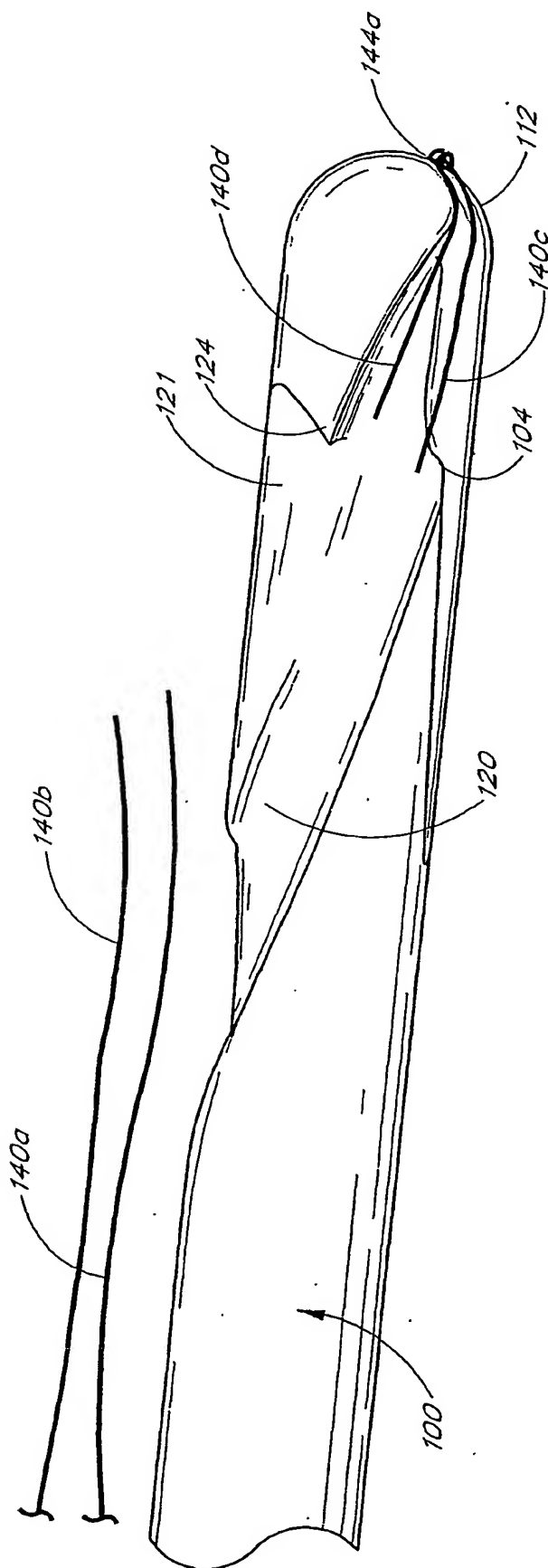


FIG. 7C

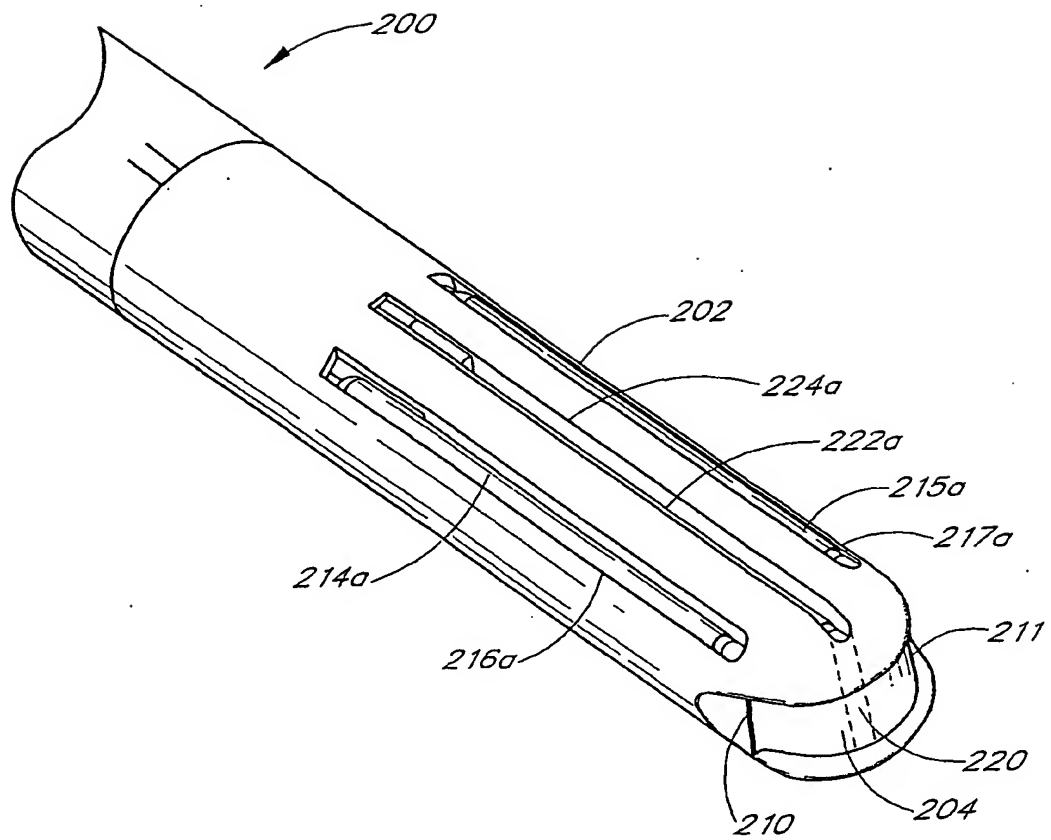
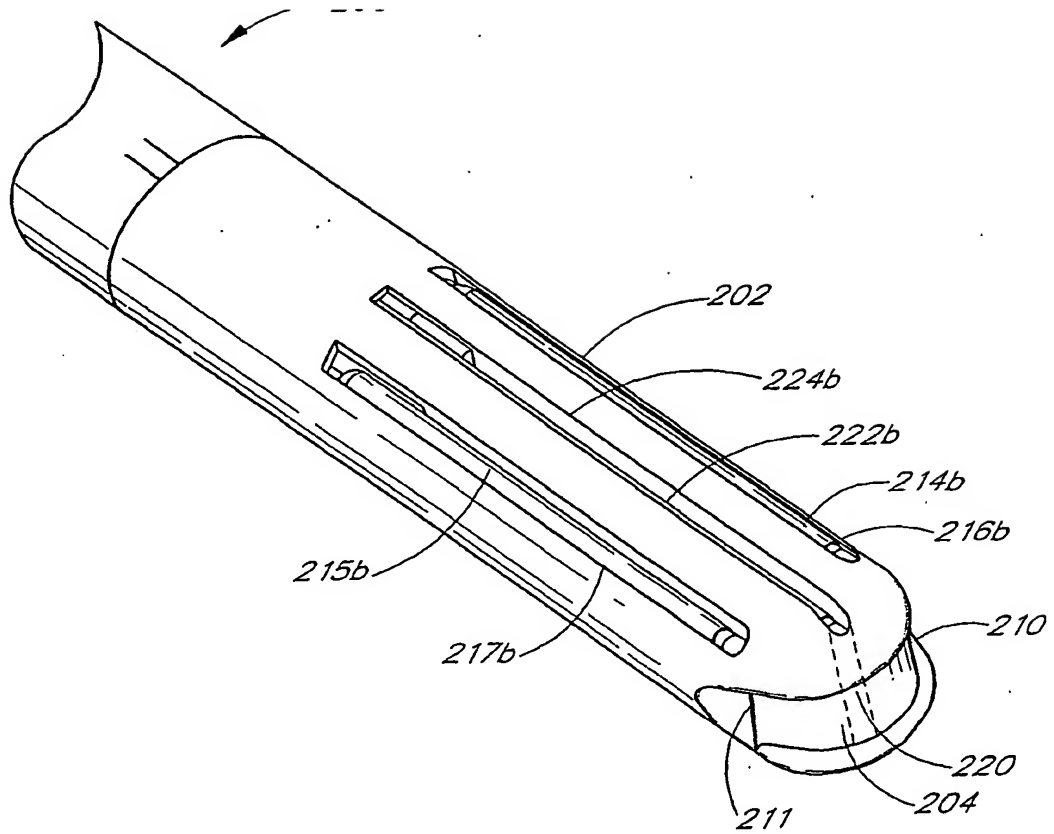


FIG. 8

*FIG. 9*

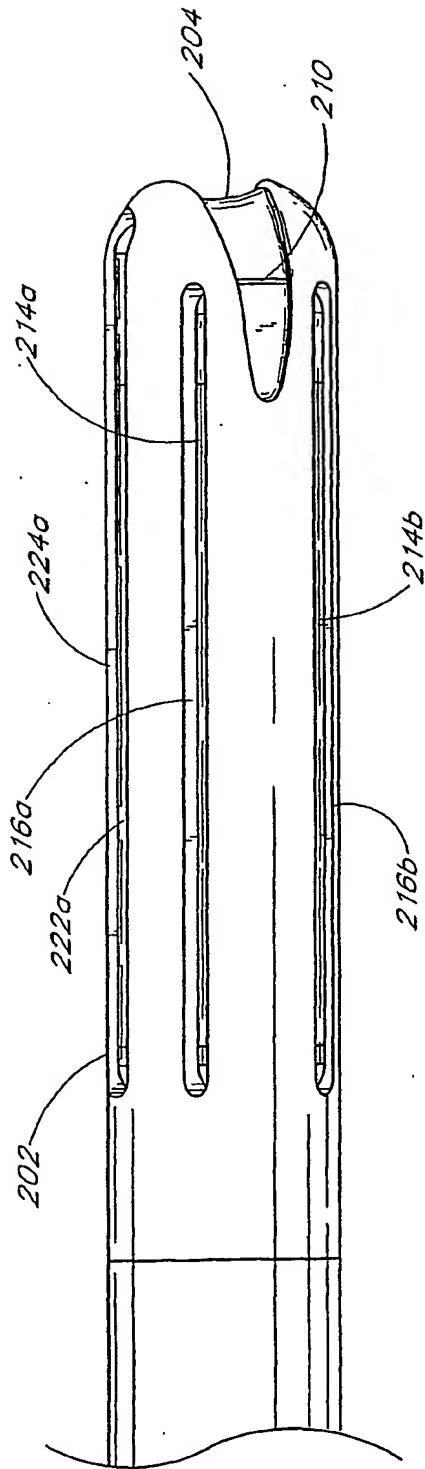


FIG. 10

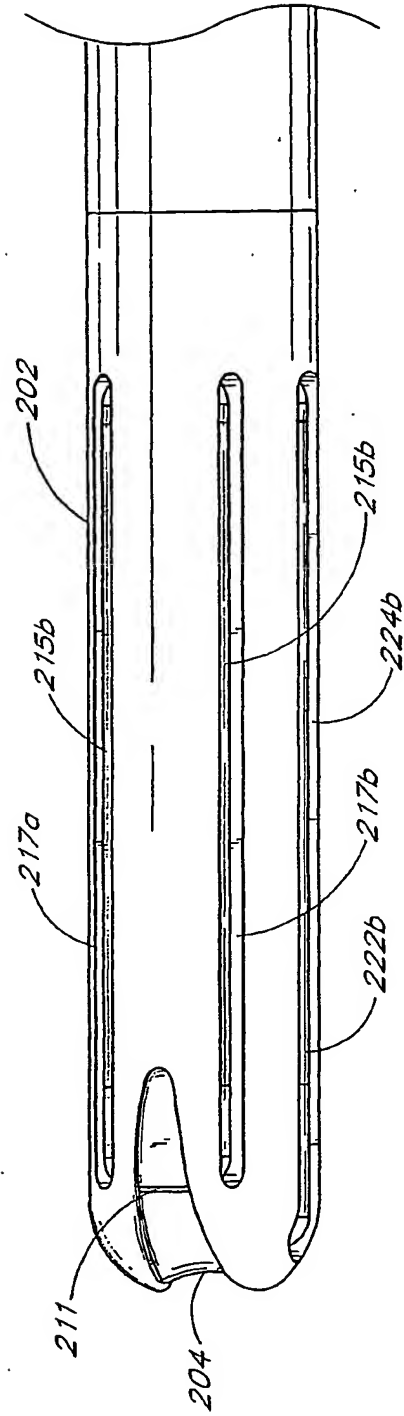
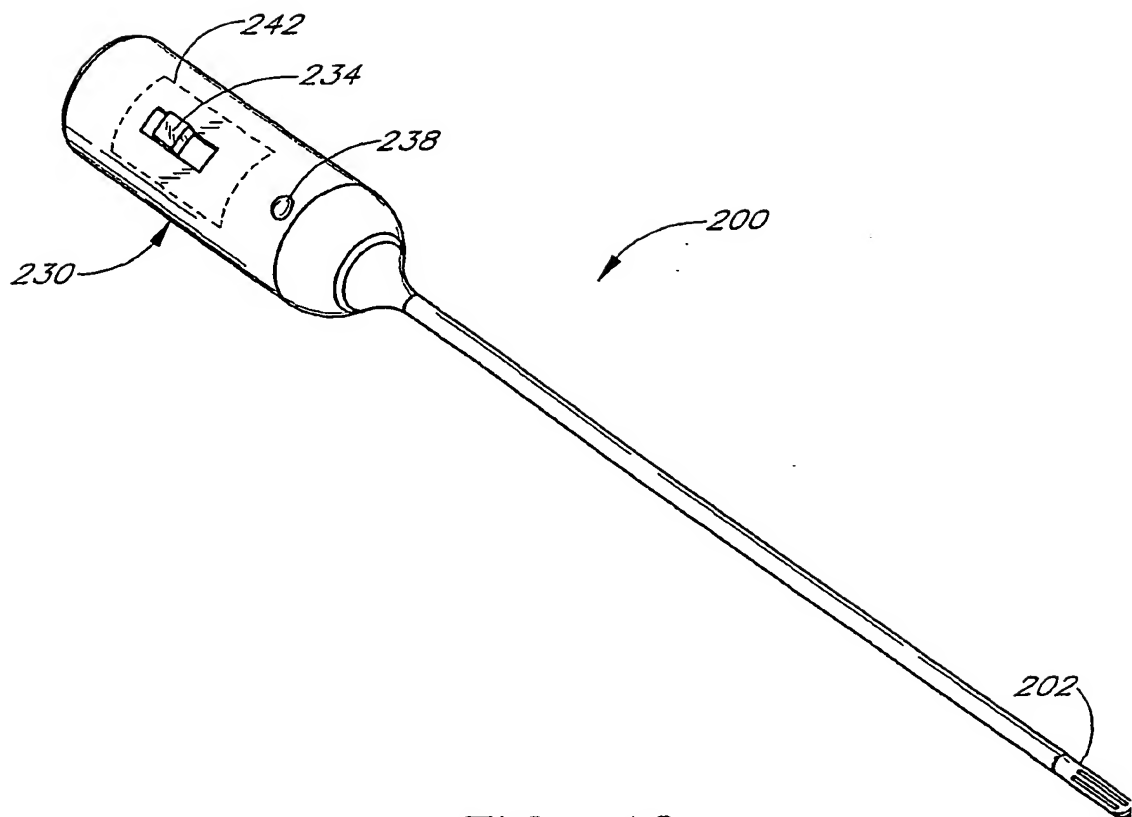


FIG. 11

*FIG. 12*

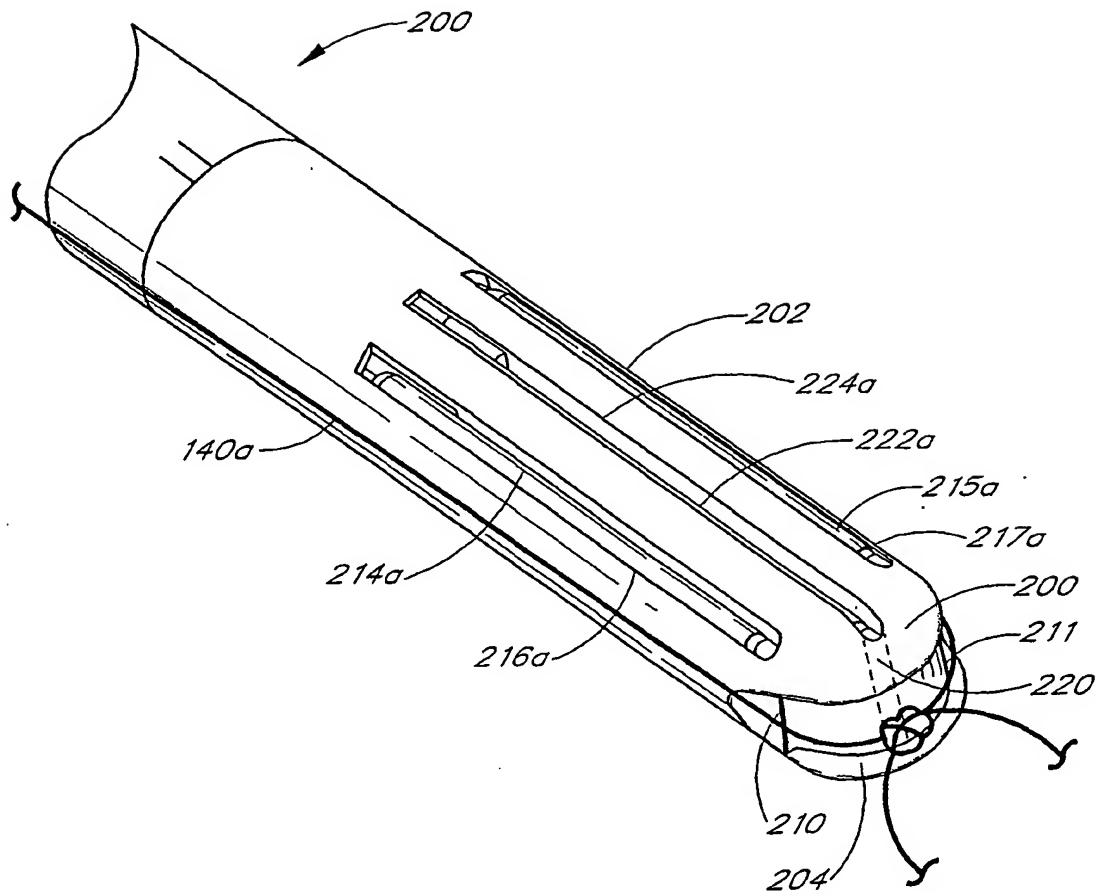


FIG. 13

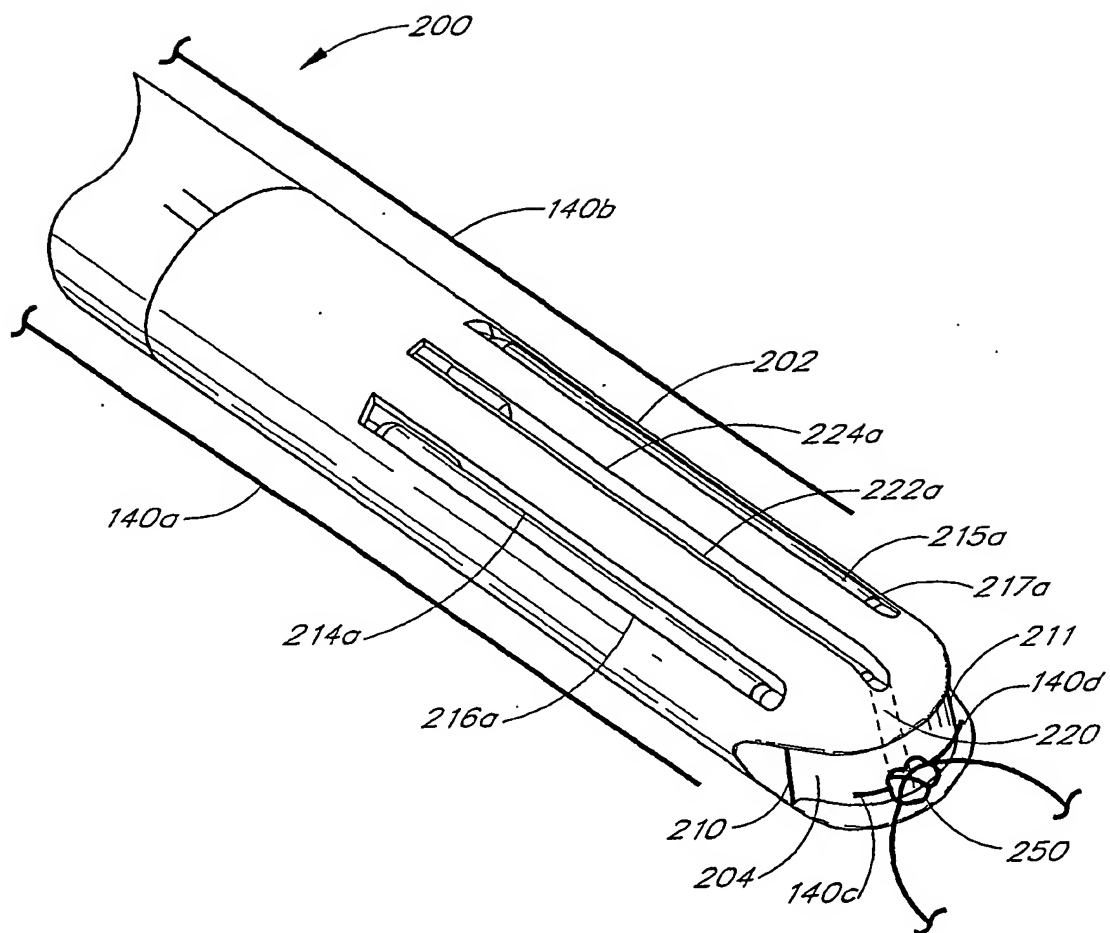


FIG. 14

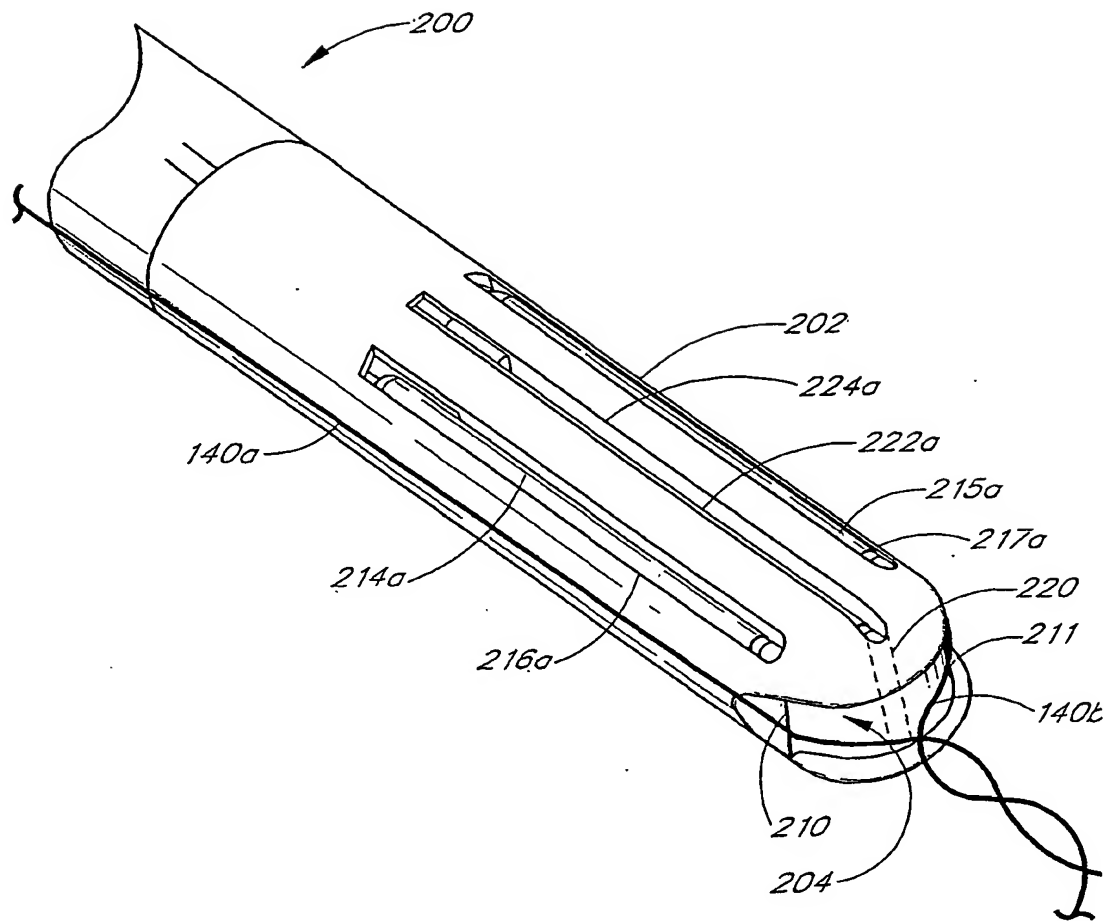


FIG. 15

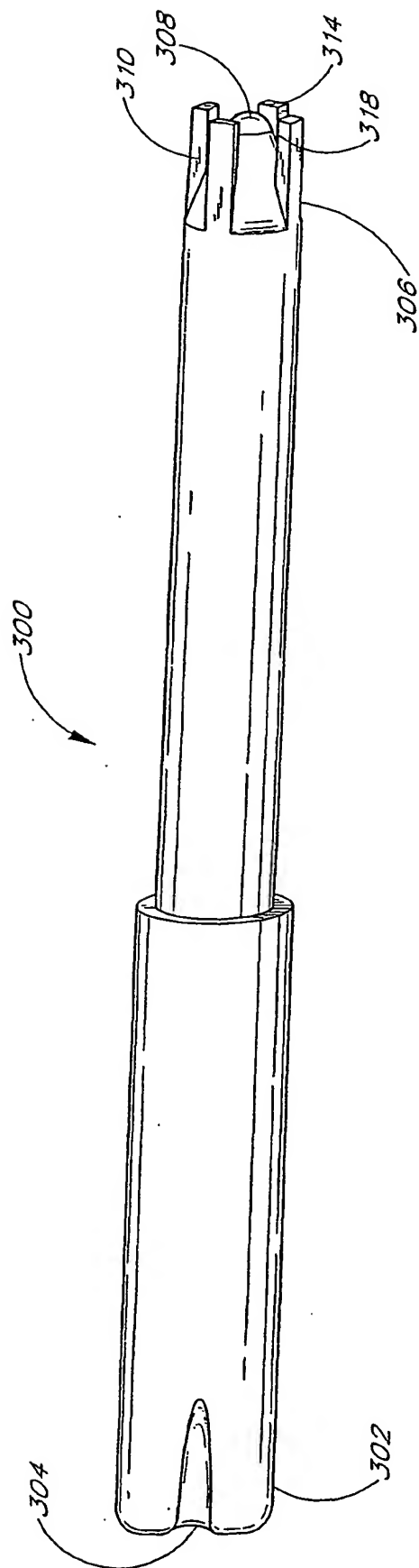


FIG. 16

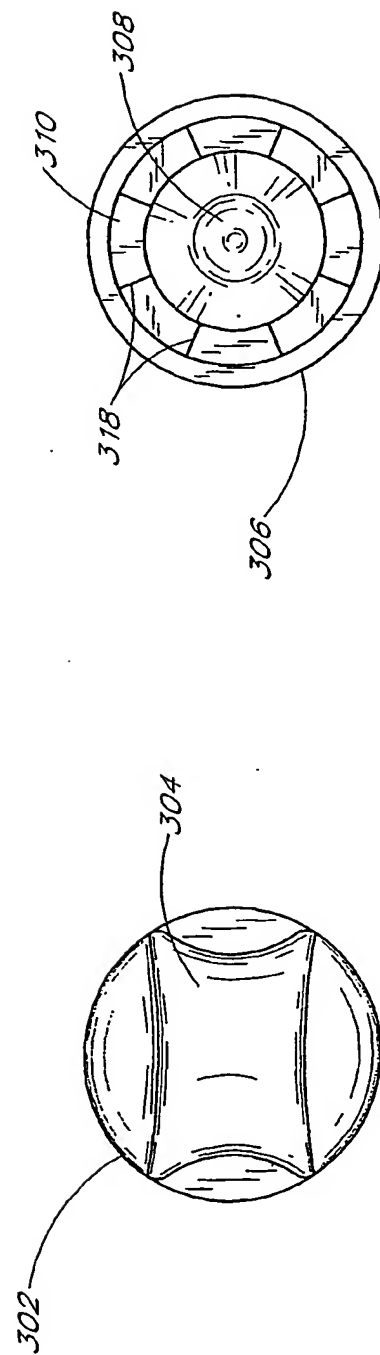


FIG. 17

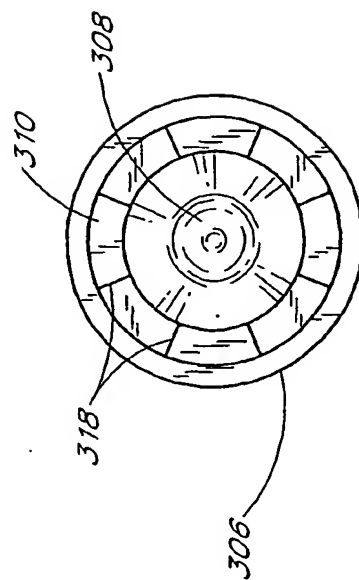
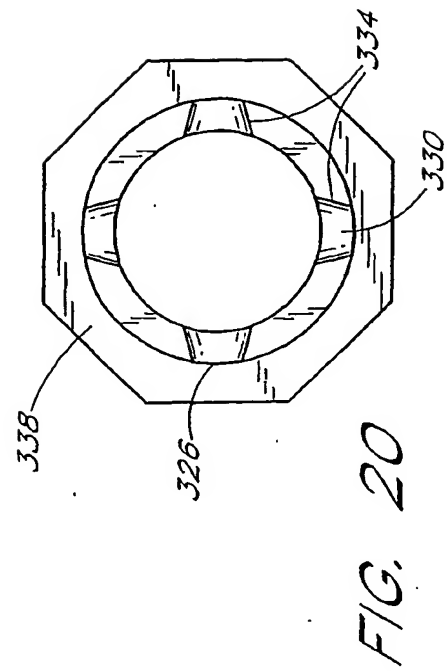
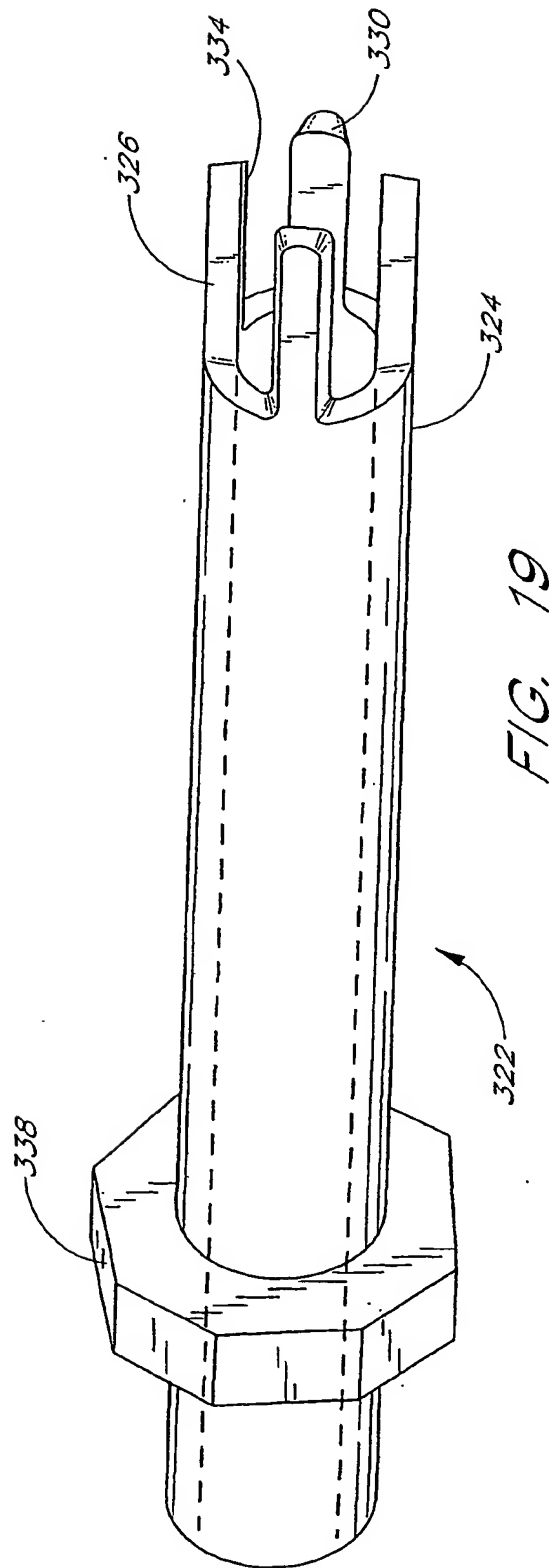


FIG. 18



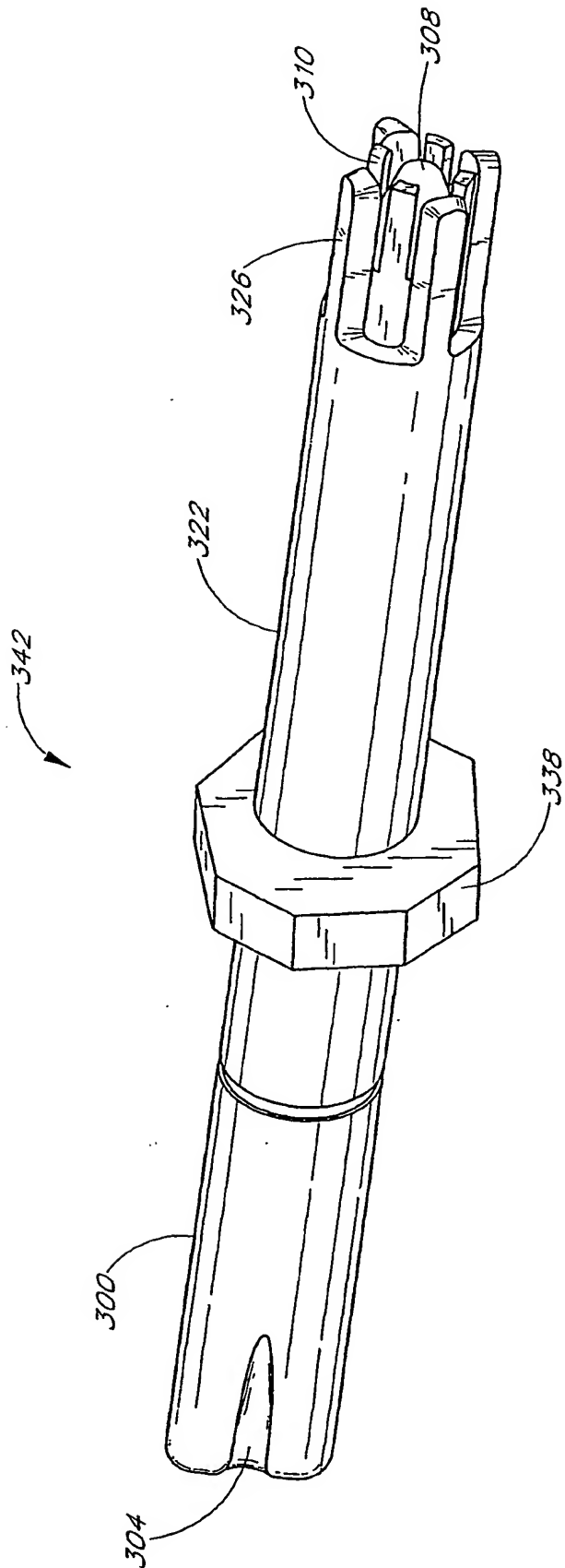


FIG. 21

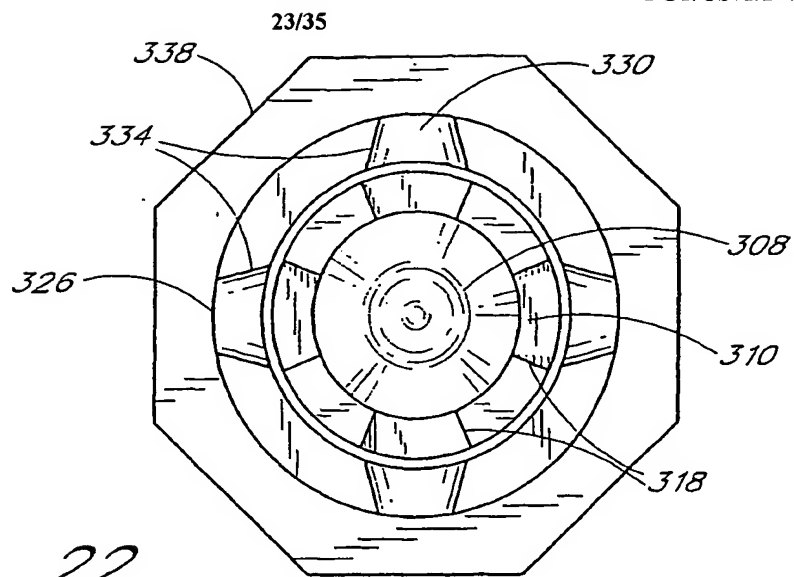


FIG. 22

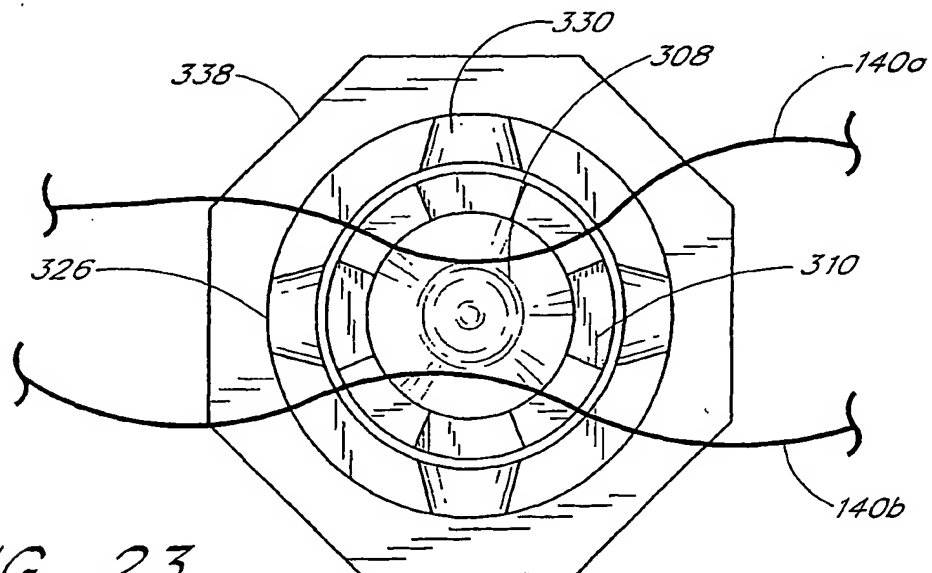


FIG. 23

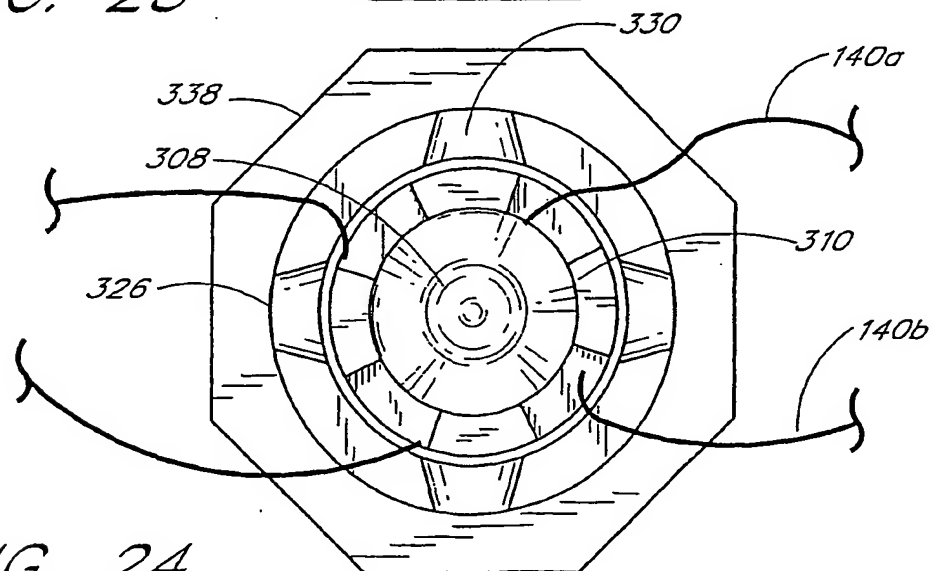


FIG. 24

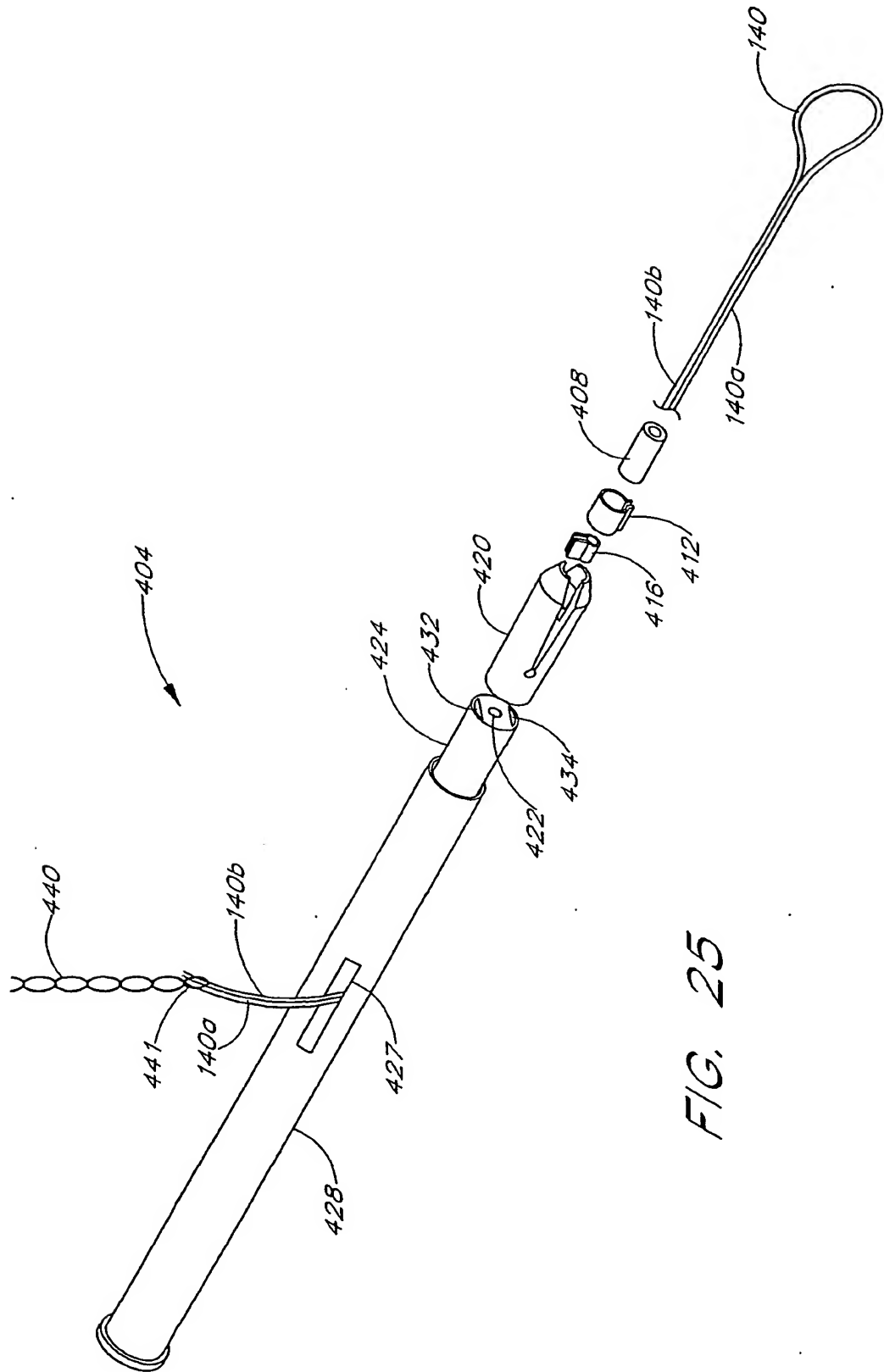
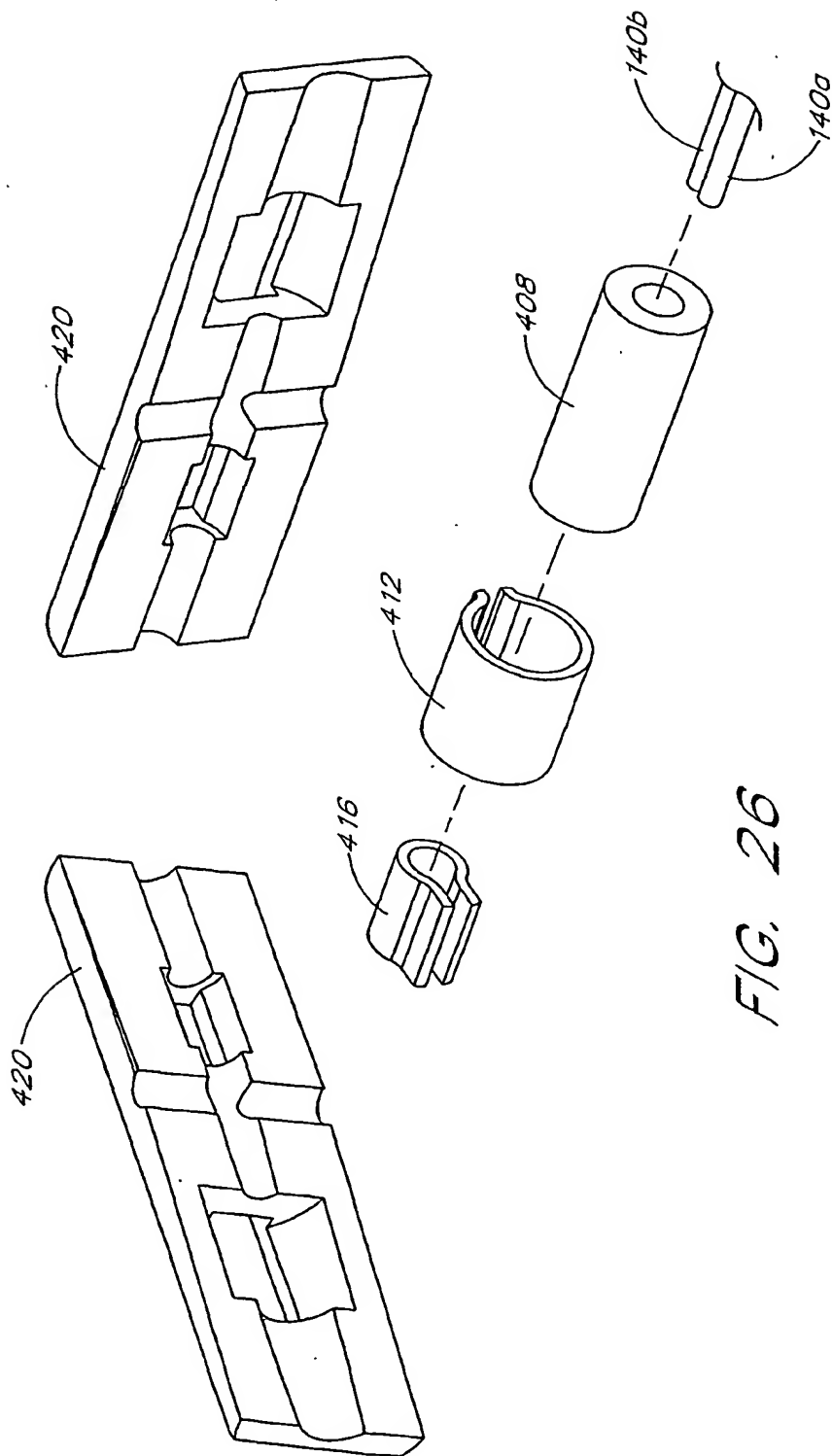
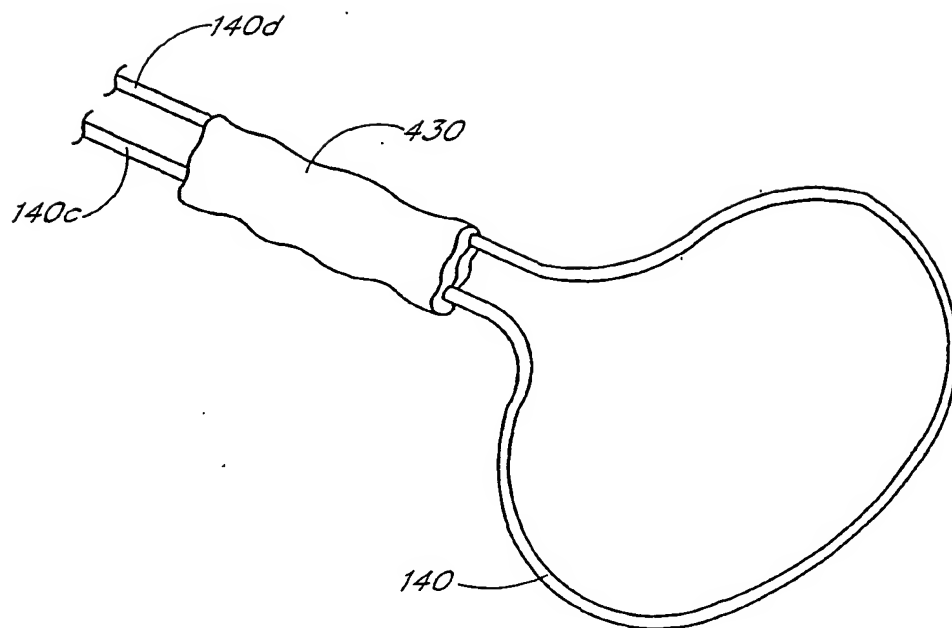


FIG. 25



*FIG. 27*

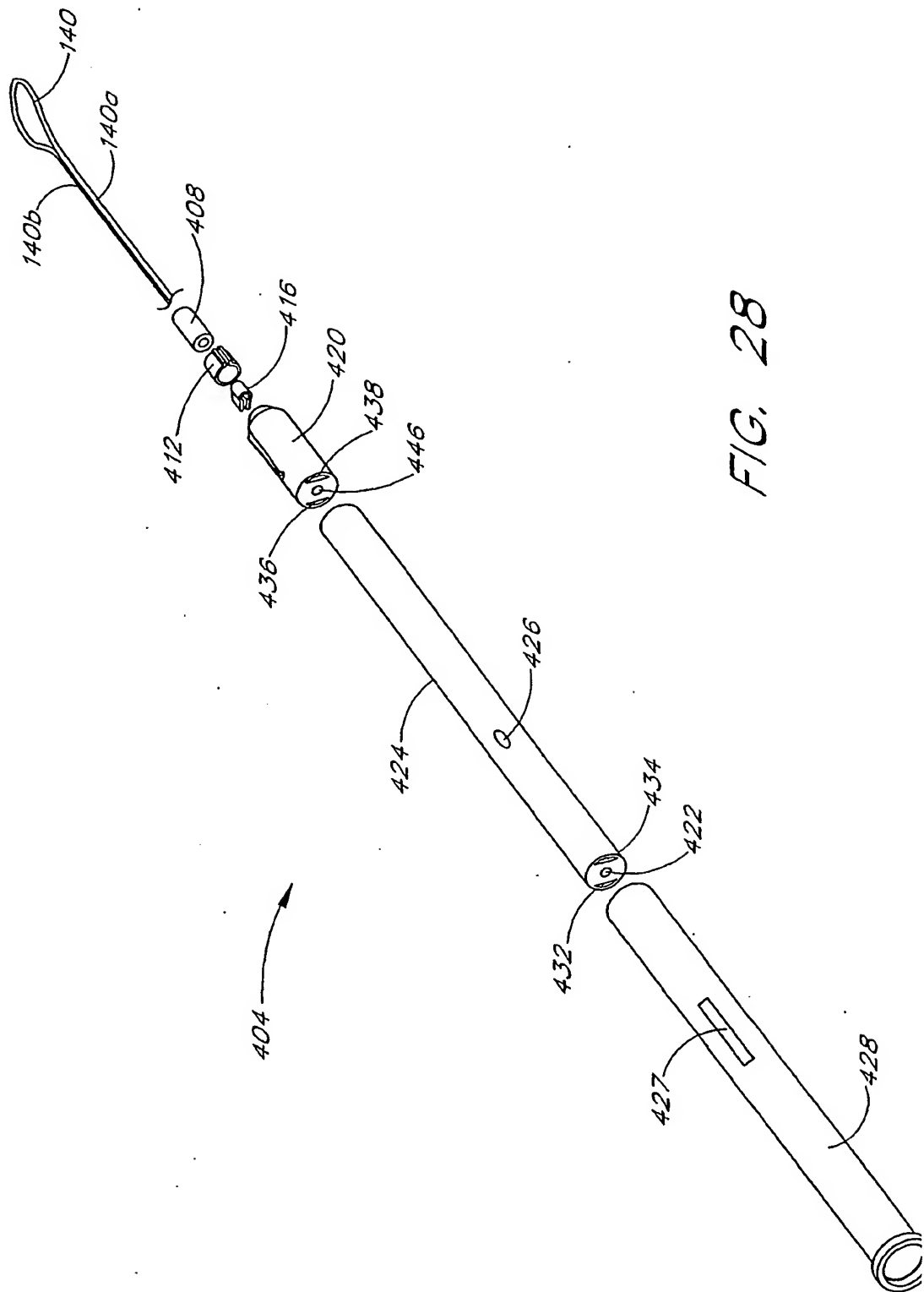


FIG. 28

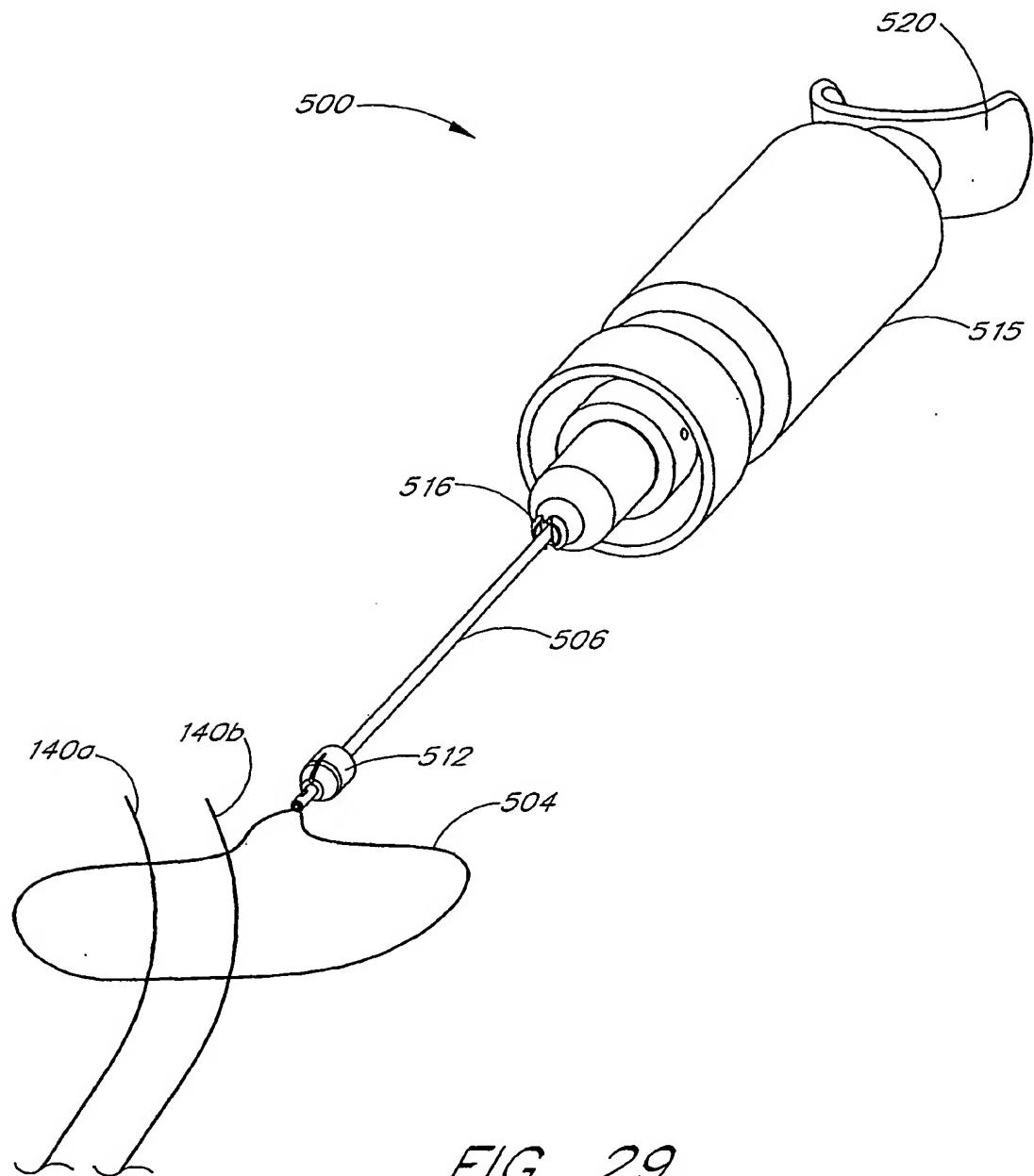


FIG. 29

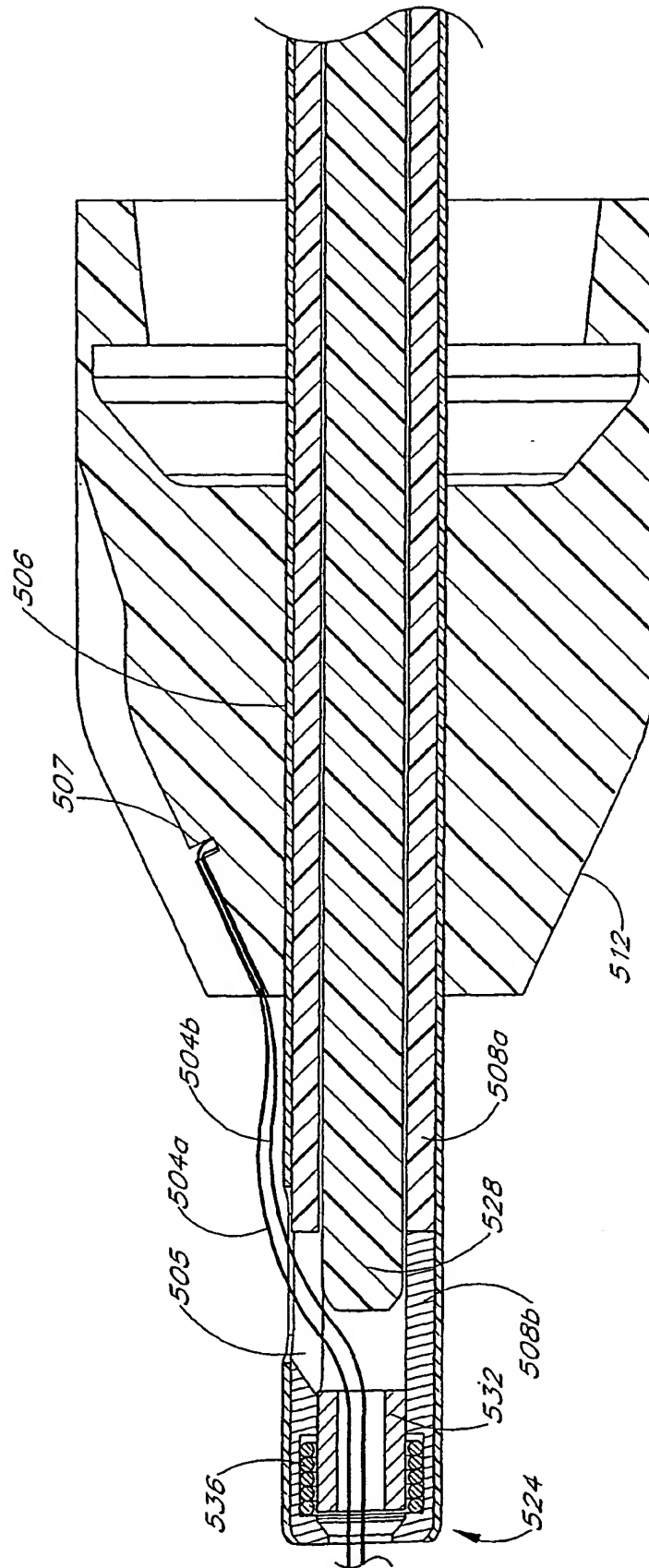


FIG. 30

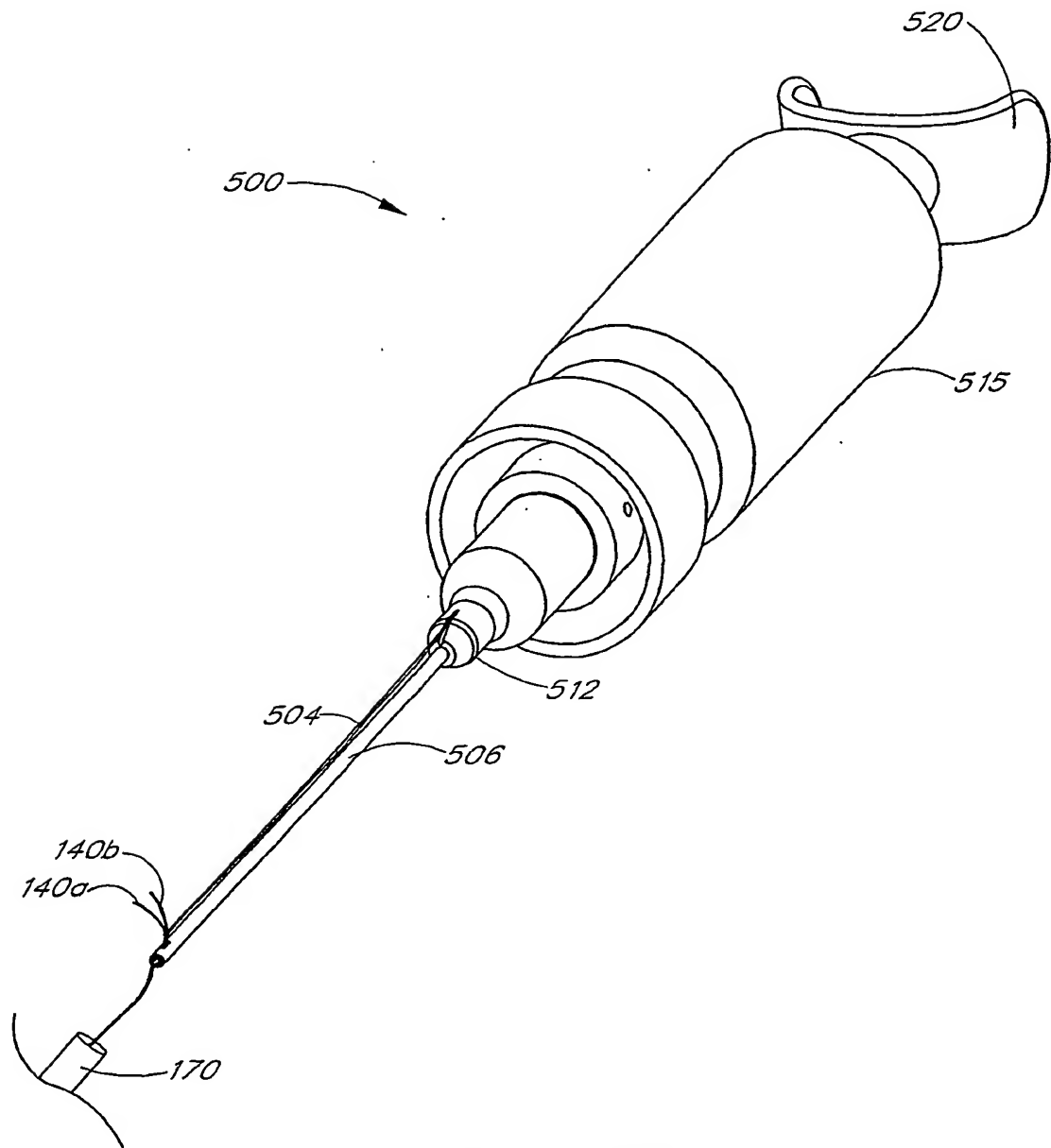


FIG. 31

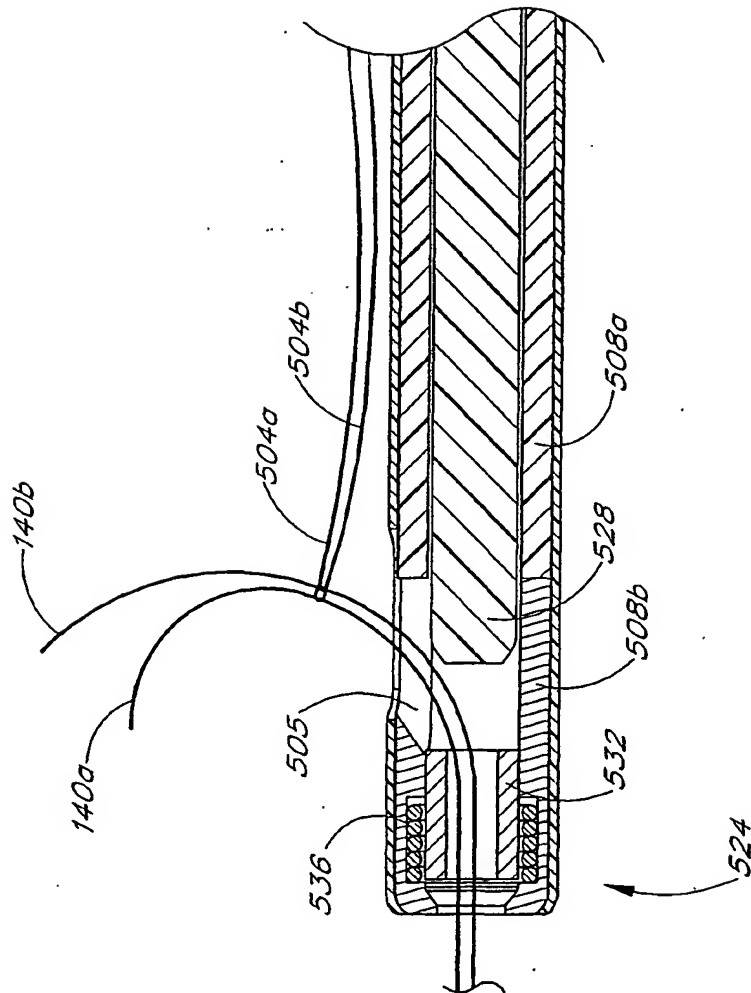


FIG. 32

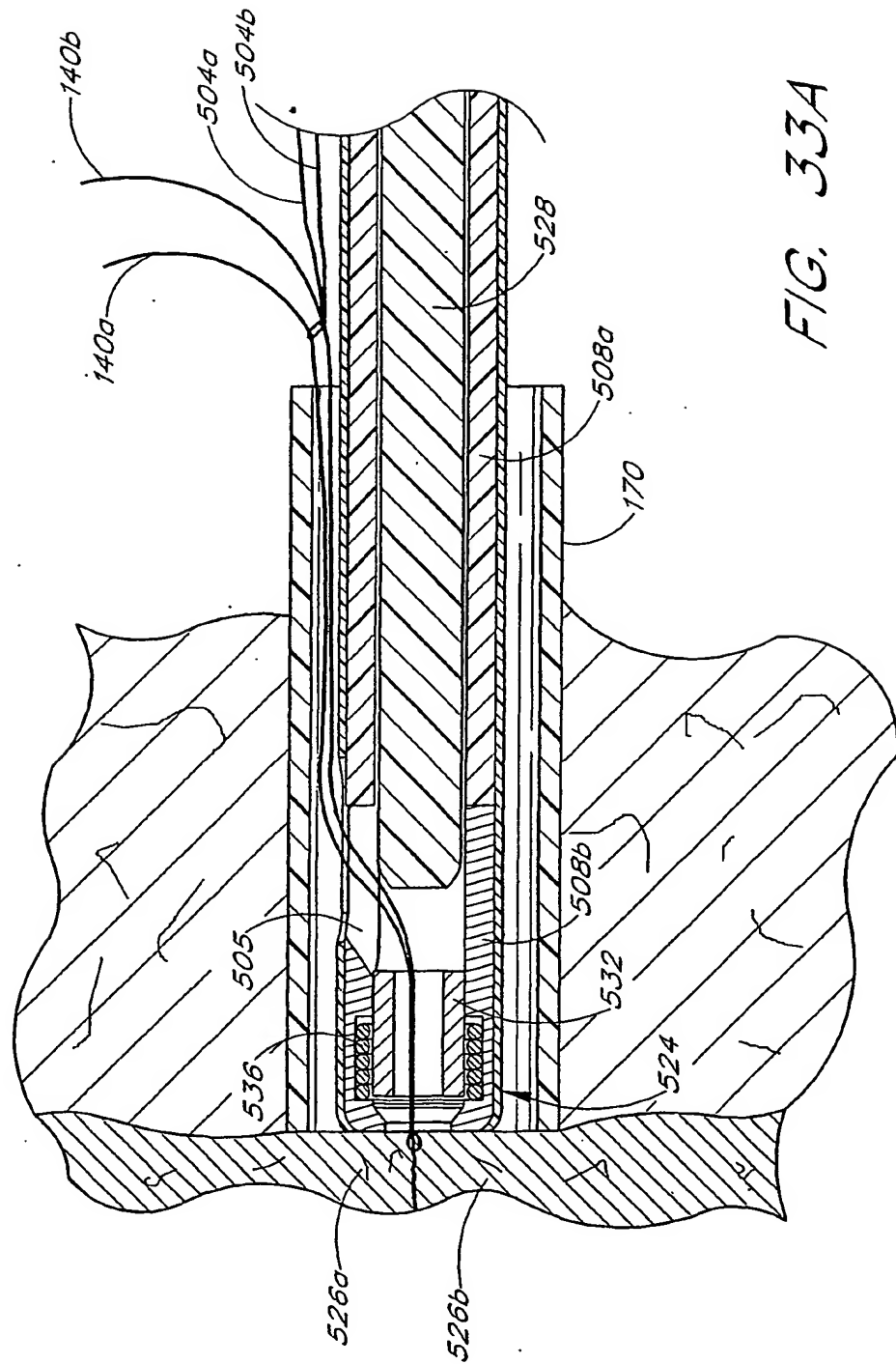


FIG. 33A

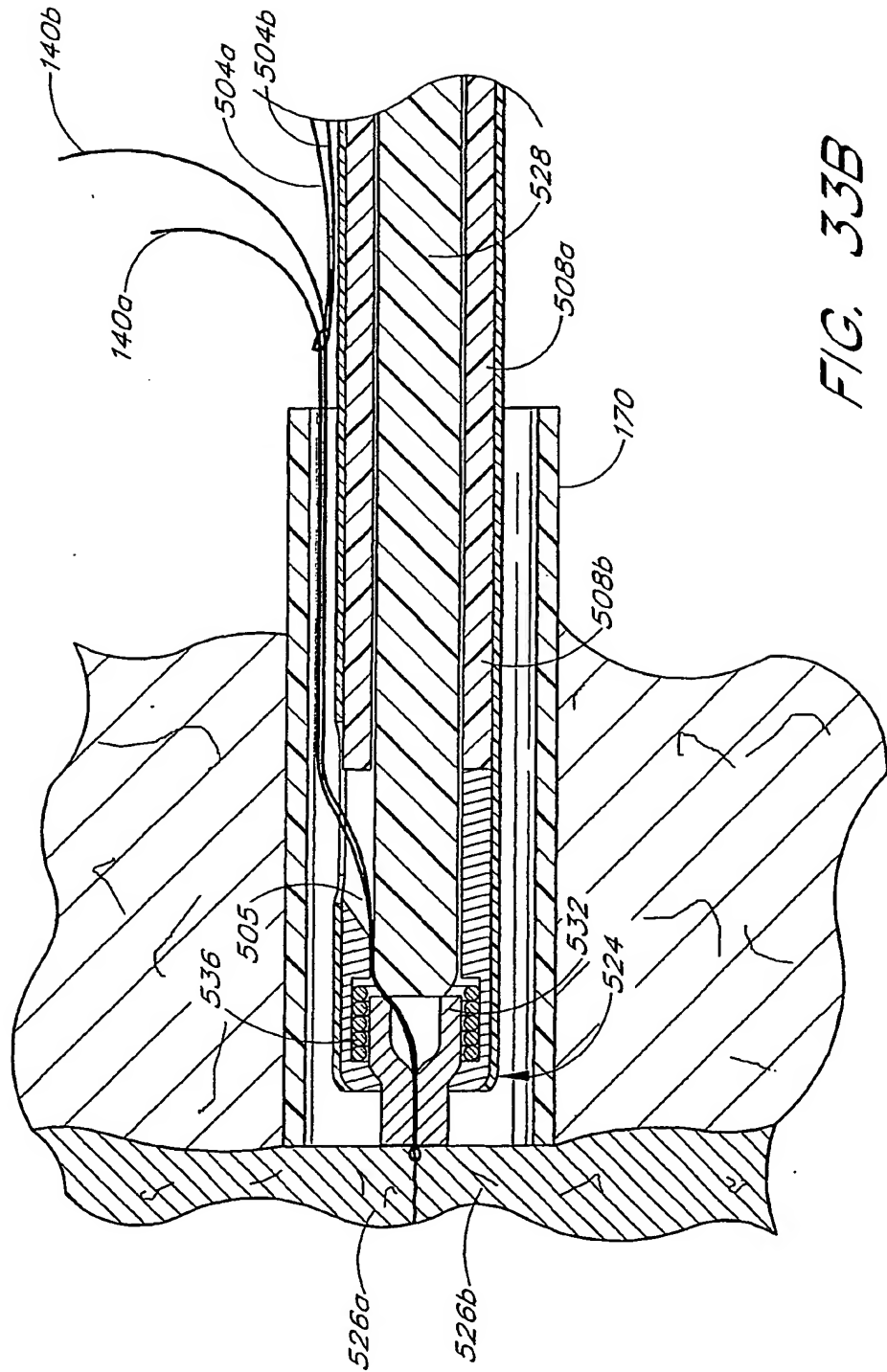


FIG. 33B

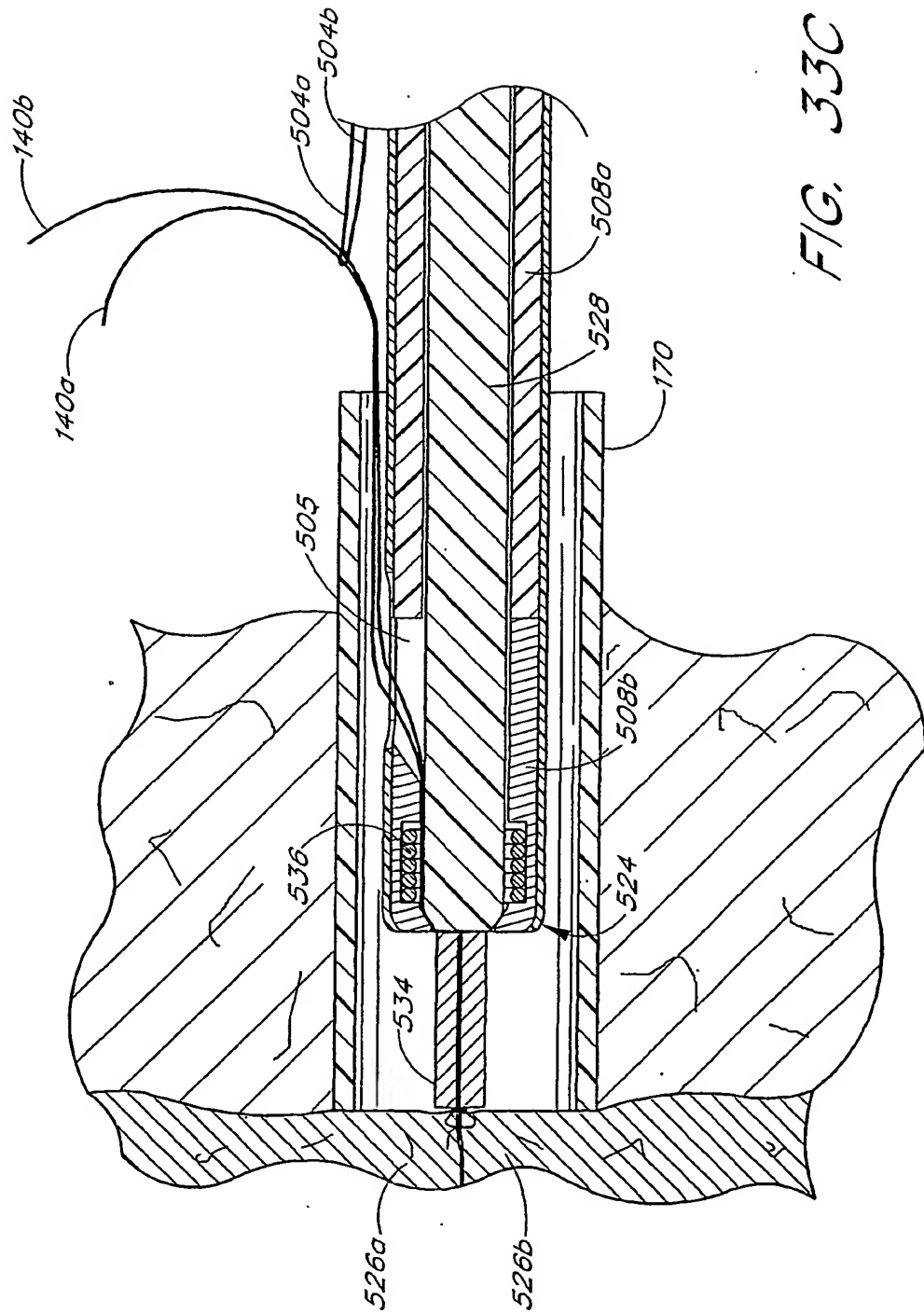


FIG. 33C

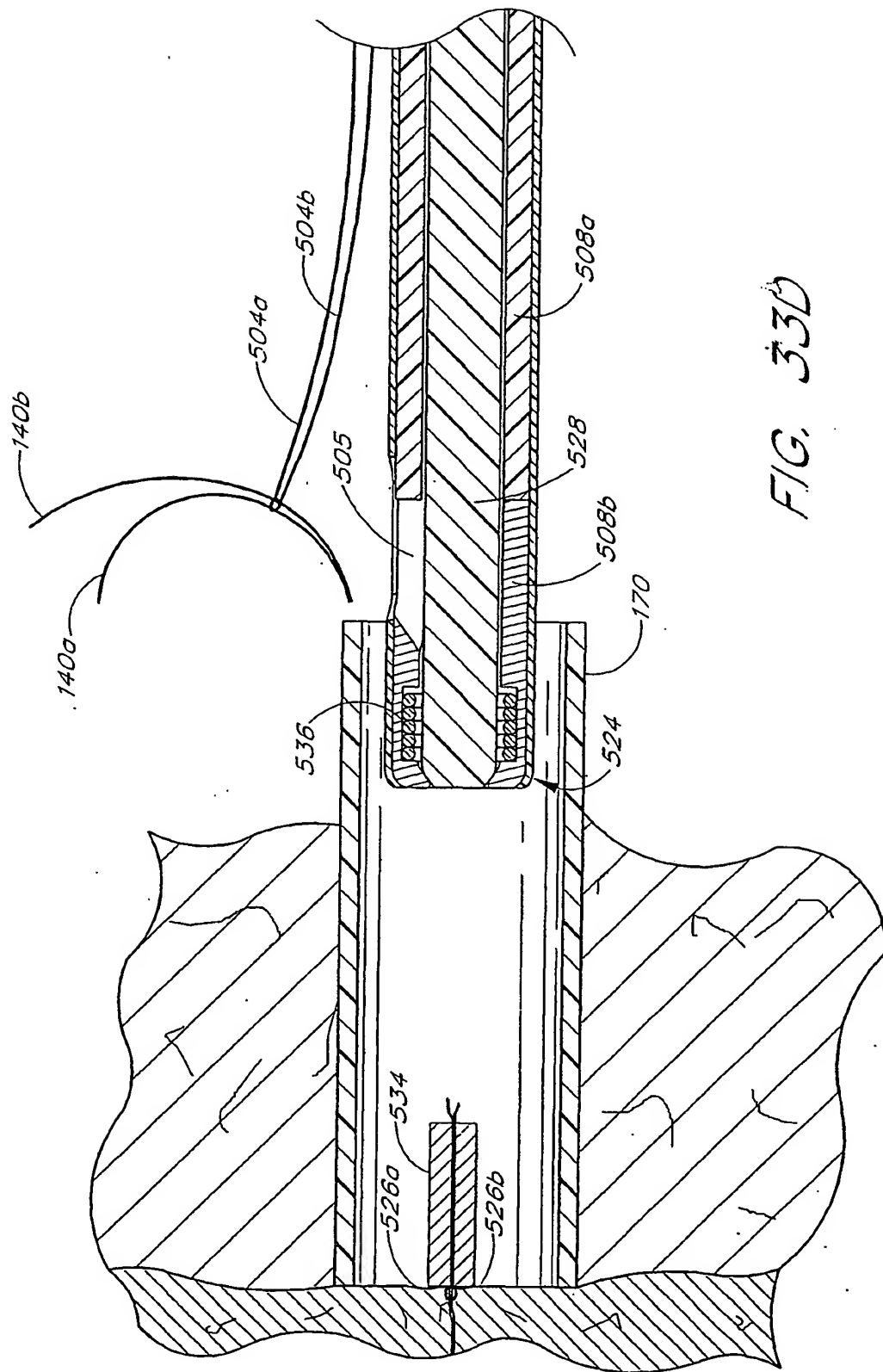


FIG. 33D

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 February 2002 (28.02.2002)

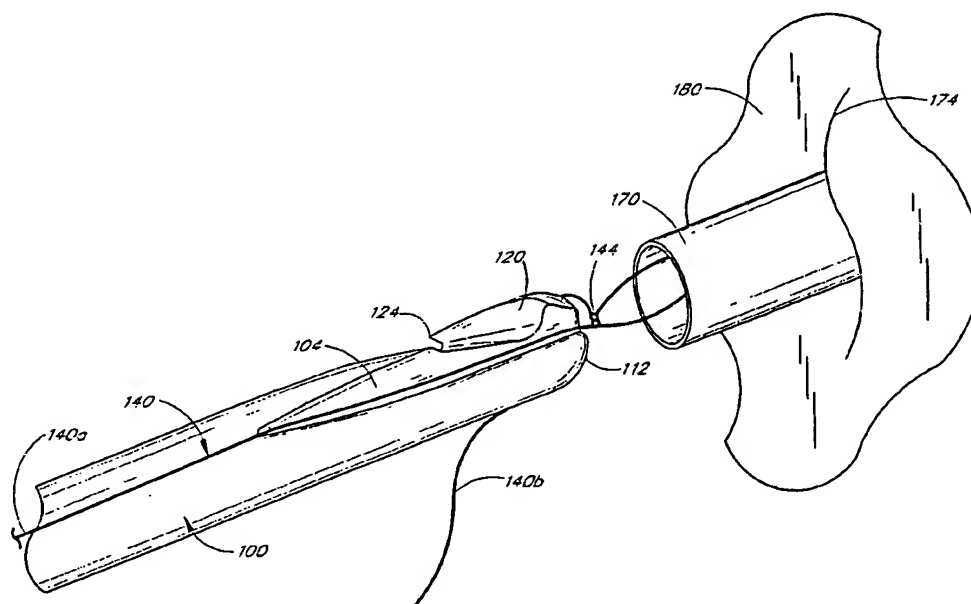
PCT

(10) International Publication Number
WO 02/15795 A3

- (51) International Patent Classification⁷: **A61B 17/04**
- (21) International Application Number: **PCT/US01/26724**
- (22) International Filing Date: **27 August 2001 (27.08.2001)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
60/228,267 25 August 2000 (25.08.2000) **US**
- (71) Applicant (*for all designated States except US*): **SUTURA, INC.** [US/US]; 17080 Newhope Street, Fountain Valley, CA 92708 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **NOBLES, Anthony, A.** [US/US]; 8686 Tern Avenue, Fountain Valley, CA 92708 (US). **DECKER, Steven, E.** [US/US]; 1295 North Amelia, Anaheim, CA 92807 (US). **PETERSON, Rod** [US/US]; 23592 Windsong, Apartment 29I, Aliso Viejo, CA 92656 (US).
- (74) Agent: **ALTMAN, Daniel, E.**; Knobbe, Martens, Olson & Bear, LLP, 620 Newport Center Drive, 16th Floor, Newport Beach, CA 92660 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EC, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CI, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: **SUTURE CUTTER**



(57) Abstract: Suture cutter embodiments (100) include elements for cutting back the leads of a suture (140) after the suture has been tied into a knot (144), e.g., as a result of drawing tissue portions together. The suture cutter (100) may include mechanisms which can be used to push and position a knot (144), so that a single device may be used to both push a knot and trim the excess material therefrom.

WO 02/15795 A3

**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) Date of publication of the international search report:

6 June 2002

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/26724

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 077 277 A (MOLLENAUER ET AL.) 20 June 2000 (2000-06-20) the whole document	4,5,7, 10-12,18
Y	---	13,14, 17,19
Y	US 4 662 068 A (POLONSKY) 5 May 1987 (1987-05-05) abstract; figures column 2, line 3-47	13,14, 17,19
A	---	4,10,18
X	WO 95 25470 A (UNIVERSITY COLLEGE LONDON) 28 September 1995 (1995-09-28) page 3, line 5 -page 4, line 27; figures --- -/--	4,6,8,9, 11,15,16

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the international search

20 March 2002

Date of mailing of the international search report

27/03/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/26724

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 439 470 A (LI) 8 August 1995 (1995-08-08) column 10, line 11-63; figures 48-50 ---	4,6,8,9, 11,15,16
X	WO 98 12970 A (THOMPSON ET AL.) 2 April 1998 (1998-04-02) page 4, line 20 -page 5, line 21; figures 2,7,8 ---	4,6,7,9, 11
X	WO 00 02489 A (AXYA MEDICAL, INC.) 20 January 2000 (2000-01-20) abstract; figures ---	18,20-24
X	US 5 669 917 A (SAUER ET AL.) 23 September 1997 (1997-09-23) figures -----	20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/26724

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6077277	A	20-06-2000	AU 4069300 A EP 1168966 A1 WO 0059383 A1	23-10-2000 09-01-2002 12-10-2000
US 4662068	A	05-05-1987	NONE	
WO 9525470	A	28-09-1995	AU 3245895 A DE 69509642 D1 DE 69509642 T2 EP 0751747 A1 WO 9525470 A1 JP 9510382 T US 5755730 A	09-10-1995 17-06-1999 16-09-1999 08-01-1997 28-09-1995 21-10-1997 26-05-1998
US 5439470	A	08-08-1995	AU 5356894 A WO 9408515 A1	09-05-1994 28-04-1994
WO 9812970	A	02-04-1998	US 5860993 A AU 4594197 A WO 9812970 A1	19-01-1999 17-04-1998 02-04-1998
WO 0002489	A	20-01-2000	AU 4982599 A EP 1094756 A1 WO 0002489 A1	01-02-2000 02-05-2001 20-01-2000
US 5669917	A	23-09-1997	CA 2141911 A1 DE 69512447 D1 DE 69512447 T2 EP 0669103 A1 US 5643289 A	25-08-1995 04-11-1999 31-05-2000 30-08-1995 01-07-1997